

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CIVIL ACTION NO 16-MD-2738 (FLW) (LHG)

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IN RE JOHNSON & JOHNSON : DAUBERT HEARING  
POWDER PRODUCTS MARKETING, : JULY 26, 2019  
SALES PRACTICES. : VOLUME 5  
----- :

CLARKSON S. FISHER UNITED STATES COURTHOUSE  
402 EAST STATE STREET, TRENTON, NJ 08608

B E F O R E: THE HONORABLE FRED A. L. WOLFSON, USDJ

A P P E A R A N C E S:

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(Continued)

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On Behalf of Defendant Personal Care Products Council

1 M O R N I N G S E S S I O N

2

3 THE DEPUTY CLERK: All rise.

4 THE COURT: Thank you. Good morning.

5 Would you call your witness.

6 MS. BROWN: Good morning, your Honor. We call  
7 Dr. Diette to the stand.

8

9 **GREGORY B. DIETTE**, called as a witness on behalf of  
10 the Defendants, having been first duly sworn,  
11 testified as follows:

12

13 DIRECT EXAMINATION

14 BY MS. BROWN:

15 Q. Good morning, Dr. Diette.

16 A. Good morning.

17 Q. We're excited to have you here today.

18 The Court already has your report and your CV  
19 as Exhibit C 18?

20 MS. BROWN: Your Honor, I can hand up another  
21 copy of the report and CV.

22 THE COURT: That would be great.

23 MS. BROWN: May I approach?

24 THE COURT: Thank you. You may proceed.

25 Q. Dr. Diette, I don't want to spend too much time

1 on your education and your experience, but would you  
2 at least introduce yourself to the Court and tell us  
3 who you are and what you do.

4 A. Sure.

5 Gregory Diette. I'm a full professor at Johns  
6 Hopkins University. I have appointments in the School  
7 of Medicine and the School of Public Health. I  
8 function in the traditional three roles there.

9 Q. You have three major roles at Johns Hopkins?

10 A. Yes. I see patients, outpatients in the clinic  
11 and also in inpatient settings as well.

12 I'm an educator. So I teach medical students,  
13 residents, fellows, the whole variety of trainees, and  
14 I'm a researcher. So I've had a full research  
15 portfolio for a couple decades.

16 Q. Are you, Dr. Diette, formally trained in the  
17 field of epidemiology?

18 A. I have a Master's degree from the School of  
19 Public Health.

20 Q. Do you do any teaching in the field of  
21 epidemiology nowadays at Johns Hopkins?

22 A. All sorts. I'm a mentor to various either  
23 junior faculty or fellows or residents. Part of that  
24 is teaching how to do a proper study, how to interpret  
25 it, how to report it.

1 I've taught in the classroom setting, for  
2 example a class called design of clinical studies that  
3 I co-directed. There are a variety of different  
4 lectures I give, and also just a lot of day-to-day  
5 hands-on support as well.

6 Q. You mentioned you are also a clinician, a  
7 practicing physician as well?

8 A. As well.

9 Q. Would you just tell us what that practice looks  
10 like?

11 A. It is a mixture of things.

12 I see outpatients that are referred to me in  
13 the clinic. I cover the physiology lab. The  
14 physiology lab is where we do exercise tests and lung  
15 function tests. I attend in the intensive care unit  
16 on the pulmonary service, taking care of pulmonary  
17 patients where we also do consults on every sort of  
18 patient in the hospital. I attend in the oncology  
19 center and then also the internal medical services as  
20 well.

21 Q. Have you conducted, Dr. Diette, your own  
22 epidemiology research?

23 A. Yes. It has been an ongoing process for the  
24 last couple of decades of doing a variety of human  
25 based research, which falls under the heading of

1 epidemiologic research.

2 Q. Can you give me the types of organizations or  
3 institutions that have funded your research over the  
4 years?

5 A. A mixture. The government organizations include  
6 NIH, the National Institutes of Health, Agency For  
7 Health Care Research and Quality, Environmental  
8 Protection Agency, and others, and then there's been  
9 private foundations and industry as well.

10 Q. Have you provided testimony to Congress  
11 concerning some of your epidemiology research?

12 A. Yes.

13 Q. Dr. Diette, has the focus of your own research  
14 been on ovarian cancer?

15 A. No.

16 Q. Does the fact that your own publications and  
17 research do not focus on ovarian cancer prevent you  
18 from being able to review and interpret the ovarian  
19 epidemiology at issue here?

20 A. Not at all. The approach to epidemiology is a  
21 fairly standard one where we are able to understand  
22 exposures of various sorts to understand all sorts of  
23 diseases and where there is risk or how to describe  
24 what the distribution of the disease is. It is  
25 important, too, in my teaching, in mentoring -- not

1 all of the teaching and mentoring is to people who  
2 take care of lung patients. I taught obstetricians,  
3 ear, nose and throat surgeons, ophthalmologists, the  
4 whole spectrum.

5 Q. Would you tell us, Dr. Diette, a little bit  
6 about your work with this MECOR organization?

7 A. That's an organization within the American  
8 Thoracic Society, and that society is our main lung  
9 society for professionals around the world. This is a  
10 program I participated in for many years where we  
11 teach epidemiologic methods to mostly physicians, but  
12 also doctoral students and some other medical  
13 professionals around the world how to do epidemiologic  
14 research.

15 Q. Have you participated in that program for a  
16 number of years now, Dr. Diette?

17 A. Several years. I traveled overseas many times  
18 to do that, and I've also done work in the United  
19 States when the mentees come to our conference each  
20 year to meet with them and help them with their  
21 research.

22 Q. The focus of that program is epidemiology?

23 A. Absolutely. We teach the basic methods. I was  
24 in charge of teaching advanced methods, and we also  
25 help them literally with their study design and with

1 interpretation of their findings and help them publish  
2 their results as well.

3 Q. Dr. Diette, do I always tease you about this  
4 picture where you are in front of a tree?

5 A. I don't know why. It is less pretentious than a  
6 white coat in a hospital. That's the one I have been  
7 using professionally.

8 Q. Okay. In addition to being a physician and an  
9 epidemiologist, do you also do some work consulting as  
10 an expert witness in litigation?

11 A. Yes.

12 Q. Can you give us an idea what percentage of your  
13 time you devote doing some of the things you are doing  
14 here today?

15 A. It varied over time. The first work I ever did  
16 was more than 10 years ago. Sometimes it is sporadic  
17 and sometimes there is more.

18 I would say currently between 10 and  
19 20 percent of my time, which includes -- my time  
20 includes weekends and nights and holidays. So I'm  
21 talking about the full amount of time that's available  
22 to me.

23 Q. Do you do expert witness work only for  
24 defendants in litigation?

25 A. No, plaintiffs and defendants.



1 Q. Have you ever, in fact, Dr. Diette, turned down  
2 someone who has approached you to do expert witness  
3 work?

4 A. All the time. Pretty regularly.

5 Q. In terms of the expert witness work that you do,  
6 do you receive any assistance in terms of the  
7 administrative aspect of that part of what you do?

8 A. Absolutely. Everything in my professional life  
9 I depend on administrative support. My work at  
10 Hopkins I have administrative help, but I can't use  
11 their services for outside work. So I do work with a  
12 company called Medical Science Affiliates that  
13 provides administrative support to do various things  
14 to help organize the materials.

15 Q. Is it important to you to carve out some time to  
16 do some of the expert consulting work that you do?

17 A. It is for me. I like it quite a bit. It is  
18 very interesting work. It is a great window for me  
19 into the legal profession and a different way -- and  
20 sometimes having to converse with people and learning  
21 how to explain things.

22 I do notice it helps me back at Hopkins when  
23 I'm explaining things to patients. You are always  
24 trying to perfect your craft in terms of how to  
25 communicate. It all fits together. It is a nice part

1 of where I've got a very diverse career otherwise in  
2 terms of research, teaching, and patient care, this is  
3 one more aspect I find satisfying.

4 Q. Dr. Diette, just to kind of give us a framework  
5 for our discussion here this morning, what was your  
6 task here in this case?

7 A. We can see it on the slide here. It was to  
8 review the epidemiological literature regarding the  
9 hypothesized connections between talc or asbestos in  
10 talc and the development of ovarian cancer.

11 Q. Did you conduct an investigation into that  
12 hypothesis, and are you prepared to discuss with us  
13 your conclusions here today?

14 A. Yes.

15 Q. Are you prepared to do that to a reasonable  
16 degree of medical and scientific certainty?

17 A. I am.

18 Q. Just give us a brief understanding, what are  
19 your conclusions having reviewed the epidemiology on  
20 talc and ovarian cancer?

21 A. I think the overarching conclusion is that what  
22 it says here, the body of relevant epidemiological  
23 evidence does not support a causal connection between  
24 perineal use of talcum powder products, whatever  
25 constituents those products may contain, in addition

1 to talc, and ovarian cancer.

2 Q. Dr. Diette, were you able to come to court  
3 yesterday for a little bit of Dr. McTiernan's  
4 testimony?

5 A. I did.

6 Q. Did you hear quite a big discussion about  
7 relevant risk and confidence intervals?

8 A. Yes.

9 Q. Before we get to that, would you run through  
10 with us the methodology that you employed in terms of  
11 your own -- reaching your own opinions here?

12 A. Generally speaking, I used a variety of methods  
13 to try to find all of the relevant epidemiologic  
14 studies using search engines, reading the papers  
15 themselves, and looking at the citations in those  
16 papers, and trying to make sure I had all of the  
17 papers. I read and analyzed every single one of the  
18 studies.

19 I also looked to see where other professional  
20 organizations, how they had approached the issue where  
21 that was relevant, and then ultimately employed a  
22 Bradford Hill-type assessment of the evidence.

23 Q. And as part of your methodology, Dr. Diette, did  
24 you review internal Johnson & Johnson company  
25 documents?

1 A. I did not.

2 Q. Was that important for you in reaching a  
3 scientific opinion on the hypothesized connection  
4 between talc and ovarian cancer?

5 A. It is not a method I know that's part of an  
6 epidemiological investigation. So it wouldn't fit  
7 into that particular question.

8 Q. In terms of the discussion that we had here  
9 yesterday, Doctor, to orient us, you recall  
10 Dr. McTiernan speaking quite a bit about relative  
11 risks and confidence intervals. Is that right?

12 A. I do.

13 Q. And one of the things I'm hoping you can help us  
14 to understand is how findings in epidemiology studies  
15 are interpreted and reported and used in medicine.  
16 Are you prepared to do that, Dr. Diette?

17 A. Yes, I hope so.

18 Q. Did you come up with what you thought was a good  
19 example or a framework for that discussion?

20 A. Yes.

21 Q. Tell us what we are looking at and why you  
22 believe it is helpful to understanding how  
23 epidemiology findings are reported and used in  
24 medicine.

25 A. Sure.

1           There is a lot to know about this study, and I  
2       picked it on purpose. I thought it would illustrate  
3       to the Court the way that professionals in my field  
4       interpret and report findings routinely. So I picked  
5       a study that was one of the ones I had reviewed. It  
6       is relevant to this matter because it is about a  
7       potential risk factor in ovarian cancer. It's also  
8       relevant because it comes from the Nurses' Health  
9       Study, which is one of the sources of cohort data.

10      Q.     Just to stop you right there, to orient us, this  
11     is a study that was looking into what? What was the  
12     investigation here?

13      A.     The question was whether or not analgesics --  
14     meaning aspirin and non-steroidal anti-inflammatory  
15     agents, things like Ibuprofen -- whether or not they  
16     are associated with the risk of ovarian cancer.

17      Q.     What were the overall conclusions of the study?

18      A.     Overall, it was kind of a mixture. Overall they  
19     found aspirin use altogether, there was no  
20     association; that it looked as if there was a  
21     protective association if you used low dose only, as  
22     opposed to conventional dose aspirin, and it looked  
23     like there was potentially a harmful effect from the  
24     use of NSAIDS for non-steroidal.

25      Q.     This is a recent study. Right, Dr. Diette?

1 A. Yes. This is from 2018, which is part of the  
2 reason I picked it also because I think these authors  
3 are careful in their use of language as they interpret  
4 their findings. And so it tells us at least in 2018  
5 in a good journal JAMA Oncology, the way that people  
6 are reporting findings.

7 Q. Does this paragraph that we have highlighted  
8 here contain a number of different epidemiological  
9 findings?

10 A. Yeah, it is great. It tell us really what their  
11 main findings are.

12 Q. Why don't you walk us through this paragraph and  
13 help us understand how epidemiologists like yourself  
14 take these numbers and translate them into a way to  
15 report and talk about their findings.

16 A. The first sentence that's highlighted, where it  
17 says "significant associations between aspirin and  
18 ovarian cancer risk were not observed." I would  
19 emphasize the "were not observed." It says, "When  
20 current versus nonuse of any aspirin was evaluated  
21 regardless of dose," and they have a hazard ratio, and  
22 the hazard ratio is analogous to a relative risk or an  
23 odds ratio. It is a little different measure, but it  
24 functions the same way. And so what they say the  
25 hazard ratio is .99 and so 1 would be no effect, and

1 here they have a 95 percent confidence interval that  
2 is .83 to 1.19. That includes 1.

3 So the language is important here. Even  
4 though it is to the left of that 1, in other words,  
5 pointing towards the protective side, they don't  
6 interpret it as protective. They interpret it as no  
7 effect, and that's in part because it's very close to  
8 1, but also because the confidence interval includes  
9 1.

10 If we go on, we will see, however, when low  
11 dose and standard dose aspirin were evaluated  
12 separately, an inverse association for low dose  
13 aspirin -- I'll pause there for a second. The inverse  
14 association is a hazard ratio of .77. That's below  
15 the 1 line. We can see the confidence interval does  
16 not include 1. That's where they use the language  
17 that "there is an inverse association."

18 Q. Doctor, if we could put some of these key  
19 take-aways on the flip chart, the sentence you are  
20 pointing to here is showing us a confidence interval  
21 that is less than 1. Correct?

22 A. That's right. The entire confidence interval is  
23 below 1.

24 Q. Tell us how epidemiologists like yourself report  
25 a finding like that where we are looking at a

1 confidence interval less than 1.

2 A. They use the word "inverse," and we might also  
3 use the word "protective" if that were appropriate  
4 which it would be in this case.

5 Q. If you are looking at a finding with a  
6 confidence interval below 1, in your field  
7 epidemiologists interpret that to be a protective or  
8 an inverse association?

9 A. Absolutely.

10 Q. Let's go on and see if we can understand more of  
11 the findings.

12 A. The rest of that sentence says: "But no  
13 association for standard dose aspirin." And here it  
14 is a hazard ratio of 1.17 with a confidence interval  
15 that includes 1.

16 Q. So here we have a confidence interval crossing  
17 1. Is that right?

18 A. The confidence interval crosses 1.

19 Q. How do epidemiologists like yourself interpret a  
20 finding where the confidence interval is crossing 1?

21 A. This way. The way that they did, to say there  
22 is no association even though that hazard ratio is to  
23 the right of 1.

24 MR. TISI: Your Honor, this is not on the  
25 reliance list, and I believe they supplemented and we



1 objected to this.

2 MS. BROWN: Your Honor, for the record, in  
3 advance of Dr. Diette's deposition we did serve a  
4 supplemental list. This article is listed as No. 3.  
5 It was provided to the plaintiffs in advance of his  
6 deposition, and they had the opportunity to discuss --

7 MR. TISI: In advance of the deposition?

8 MS. BROWN: Yes.

9 MR. TISI: That's fine.

10 THE COURT: Thank you.

11 BY MS. BROWN:

12 Q. Picking back up where we were, and to orient  
13 ourselves, Dr. Diette, you were explaining to us in  
14 your world and in terms of real world understanding of  
15 these epidemiology findings a confidence interval  
16 below 1 is showing a protective or an inverse  
17 association?

18 A. That's right.

19 Q. A confidence interval crossing 1 -- and we spoke  
20 a lot about that yesterday with Dr. McTiernan -- would  
21 show or be interpreted as no association. Correct?

22 A. Exactly.

23 Q. Then if you continue on, do you have another  
24 finding to help us understand?

25 A. It is the final point here.

1           The last finding here is that current use of  
2   nonaspirin NSAIDS was positively associated with risk  
3   of ovarian cancer compared with nonuse. And here the  
4   hazard ratio is 1.19, but the 95 percent confidence  
5   interval does not cross 1. And so here it is a very,  
6   very similar hazard ratio to the one right before:  
7   1.17 and 1.19 are nearly identical, but the words they  
8   use are important because they say there is no  
9   association for the 1.17 when it crossed 1. And they  
10   say it is positively associated in the one that did  
11   not cross 1.

12   Q.     Dr. Diette, to round out our chart then this  
13   study and in your world, when we have a confidence  
14   interval greater than or equal to 1, that is reported  
15   as a positive association. Is that right?

16   A.     It is. I thought this study showed it in a  
17   nutshell. It showed each one of those examples very  
18   succinctly and it came from a highly credible study in  
19   a highly credible journal, and it is current 2018. So  
20   this is the current way we express ourselves.

21           THE COURT: Thank you for that clarification,  
22   so I understand.

23           The fact that it is on 1 when you say cross,  
24   it has to have something before the 1, less than the 1  
25   and across, that's the crossover. It can't just start

1 at the 1.

2 THE WITNESS: It has to go either from below  
3 up above it or from above down below it. Because the  
4 p-Values that --

5 THE COURT: I think I understand. It has to  
6 go on one side or the other to make it happen and that  
7 1 is within it. It can't just have 1 as the number?

8 THE WITNESS: Exactly right.

9 BY MS. BROWN:

10 Q. To follow up on Her Honor's question, in  
11 reporting a positive association where the confidence  
12 intervals are equal to or greater than 1, the findings  
13 are interpreted as a positive association. Correct?

14 A. Correct.

15 Q. Just to refresh, where the confidence interval,  
16 as Her Honor was asking about, crosses 1, those  
17 findings are interpreted as showing no association.  
18 Right?

19 A. Exactly.

20 Q. And where the confidence interval, the entire  
21 interval is below 1, those findings are interpreted as  
22 showing a protective or an inverse association. Is  
23 that fair?

24 A. Exactly right.

25 Q. Now, another way to talk about these confidence

1 intervals, Dr. Diette, is to use the term "statistical  
2 significant." Is that fair?

3 A. It is.

4 Q. Would it also be fair, then, to say where your  
5 confidence interval is crossing 1, there is no  
6 statistical significance?

7 A. That's exactly right.

8 Q. Many of the studies that Dr. McTiernan put up  
9 yesterday had confidence intervals crossing 1; and  
10 would you interpret those to be non-statistically  
11 significant findings?

12 A. Yes. Each one of those for which that is true  
13 would be non-statistically significant.

14 Q. How would you then interpret that in sort of  
15 regular people's speak?

16 A. We would say there was no association found  
17 within that particular study.

18 Q. Does this mean, Dr. Diette, that we should draw  
19 a bright line at statistical significance and keep  
20 everything that reaches statistical significance and  
21 throw out any study that doesn't achieve statistical  
22 significance?

23 A. All the studies provide information, but it is  
24 one part of the information you get from the study.

25 Q. And in conducting your review of the

1 epidemiology as it relates to talc and ovarian cancer,  
2 did you employ a bright line rule to weight or value  
3 studies with statistical significance differently or  
4 better than those that did not reach statistical  
5 significance?

6 A. I tried to observe which ones were and which  
7 ones were not. I didn't exclude any in particular. I  
8 just noted which ones were and which ones were not  
9 significant.

10 Q. Why is it important for you as an epidemiologist  
11 to take note of whether or not a study is achieving  
12 findings that are reaching statistical significance?

13 A. Because within that particular study the authors  
14 of the study have conducted it in a way that they are  
15 going to be willing to communicate that the finding  
16 they have either does or doesn't endorse the idea  
17 there is a difference in the two groups they are  
18 looking at. And so this is the convention for saying  
19 there is not a difference that they can express.

20 Q. I know you had the opportunity to review some of  
21 plaintiffs' briefing in this matter. Is that right?

22 A. Yes.

23 Q. Did you see the argument that was being advanced  
24 in terms of abandoning the concept of statistical  
25 significance?

1 A. I did.

2 Q. Is that a concept you are familiar with in your  
3 field, Dr. Diette?

4 A. I have been familiar with that idea in my entire  
5 career.

6 Q. In your field is it generally accepted that we  
7 should abandon the concept of statistical  
8 significance?

9 A. No, not in July 2019. What you are discussing  
10 is something that is a proposition and that may  
11 happen. As of right now that is not the case.

12 Q. Have you understood this to be a theoretical  
13 discussion that has gone on in your world for decades?

14 A. It is a great one. The idea is that you are  
15 trying to have a system that explains something about  
16 your data, and this is the system we have right now.  
17 I think there is a good and appropriate craving for  
18 something better always, and I think that is what is  
19 going on.

20 Q. In terms of your work that you had funded by  
21 institutions like the National Institutes of Health,  
22 and other government associations, have you reported  
23 your findings in terms of whether or not they reached  
24 statistical significance?

25 A. Routinely, yes.

1 Q. In terms of your review of the talc and ovarian  
2 cancer epidemiology, were the findings in those  
3 studies reported with confidence intervals that would  
4 suggest or indicate whether or not those findings  
5 reached statistical significance?

6 A. 100 percent of the studies had either confidence  
7 intervals or p-Values or both which is conveying  
8 statistical significance.

9 Q. Dr. Diette, with this framework in mind, I want  
10 to ask you some questions about some of the  
11 conclusions in the epidemiology studies that you  
12 reviewed and relied on here.

13 Were you here yesterday, Dr. Diette, and did  
14 you hear Dr. McTiernan's conclusions about what the  
15 epidemiology shows in terms of causation?

16 A. Yes.

17 Q. Did you understand her opinion to be that based  
18 on the talc epi in part, that there is a causal  
19 association between talc and ovarian cancer?

20 A. That's what I understood.

21 Q. Do the epi studies themselves report on whether  
22 or not they have found a causal association?

23 A. I think there's a lot of cases where the authors  
24 appropriately point out to the uncertainty that still  
25 remains and it spans a couple of decades of reporting,

1 that sort of uncertainty.

2 Q. What are some of the examples of what the epi  
3 studies themselves conclude?

4 A. Those top two are two of the most recent  
5 meta-analyses. The first one says that it is unclear  
6 whether a statistical association exists; and, if so,  
7 whether it can be interpreted as reflecting some form  
8 of bias or causal relationship. So it is not clear  
9 it's been established by that statement there is  
10 causation.

11 The second one is a little clearer even  
12 saying --

13 THE COURT: You should use the names of the  
14 studies for the record. These are just PowerPoints  
15 right now.

16 Q. I'll jump in and help you on that score,  
17 Dr. Diette.

18 For example, if we look at the Berge 2018  
19 article at A-11, page 3, what do the authors of that  
20 recent meta-analysis say about a potential causal  
21 relationship between talc and ovarian cancer?

22 A. Unclear whether a statistical association exists  
23 and whether it can be interpreted as reflecting some  
24 form of bias or a causal relationship.

25 Q. And one of the studies Dr. McTiernan referred to



1 quite a bit yesterday was a meta-analysis from 2018 by  
2 Penninkilampi.

3 MS. BROWN: And that is, for the record,  
4 located at A 109, page 3.

5 Q. What do the authors of that study say about  
6 whether there is a causal link between talc use and  
7 ovarian cancer?

8 A. That it has not yet been established.

9 Q. And in your review of all of the epidemiology  
10 studies, Doctor, do you see consistent conclusions to  
11 those which we just read?

12 A. I think they are appropriately concerned in the  
13 studies about whether or not causation can be  
14 established.

15 Q. I want to talk now about, Dr. Diette, in your  
16 report, which Her Honor has, and which we have marked  
17 as C 18, did you conduct a full Bradford Hill  
18 analysis?

19 A. I did.

20 Q. We've already had Dr. Neel in here addressing  
21 part of that and we have Dr. Saenz coming next week,  
22 so I want to concentrate with you on a couple of areas  
23 of that analysis today. Is that okay?

24 A. Absolutely.

25 Q. Let's start with strength of association. Why

1 don't you start by telling us, in your view, is that a  
2 good place to start when, when you are doing this kind  
3 of analysis?

4 A. It is a good starting point because the Bradford  
5 Hill considerations start with the notion that once an  
6 association has been established that that is the  
7 jumping off point for doing a Bradford Hill type of  
8 analysis. So the strength becomes one of the  
9 important anchor points of how you are going to  
10 proceed.

11 Q. Dr. McTiernan put up a slide yesterday that  
12 indicated that she weighs this Bradford Hill factor as  
13 one of the highest. Do you agree with that?

14 A. I do. I think this is a very high one.

15 Q. In your view, Dr. Diette, is it possible to  
16 properly apply the Bradford Hill criteria and  
17 conclude, based on this epidemiology, that the  
18 association between talc use and ovarian cancer is  
19 strong?

20 A. No. It is objectively weak in certain of the  
21 studies and not existent in others.

22 Q. First of all, is there a bright line rule in  
23 terms of what is a strong association and what is a  
24 weak association?

25 A. There isn't an exact cut-off.

1 Q. Do you get any guidance, for example, from the  
2 Bradford Hill article itself?

3 A. I think it was a very helpful way to express  
4 what he was trying to convey; where, for example, he  
5 mentioned a 200 fold increase was a large effect, and  
6 that also saying in cigarette smokers it was 9 to 10  
7 times the rate of lung cancer in smokers compared to  
8 nonsmokers, and 20 to 30 in heavy smokers. Those I  
9 thought were good examples of what's clearly a strong  
10 association.

11 Q. You mentioned relative risks and odds ratio like  
12 200 or 10. Is that right?

13 A. Exactly.

14 Q. Has there been a positive relative risk reported  
15 in all of the studies that have been done on talc and  
16 ovarian cancer?

17 A. Sure. In certain of the case-controls have a  
18 positive one.

19 Q. What number are we looking at in terms of the  
20 talc and ovarian cancer literature?

21 A. The summaries of that are in the 1.2 to 1.3  
22 range.

23 Q. Have some of the authors of the talc  
24 epidemiology commented on whether that kind of a  
25 relative risk, 1.2, 1.3, is considered strong?

1 A. Yes. This is an example here from Berge saying  
2 their meta-analysis showed a weak but statistically  
3 significant association.

4 Q. One of the things we heard about yesterday,  
5 Dr. Diette, was instances like HRT and secondhand  
6 smoke where studies have produced a low relative risk.  
7 Were you here for that testimony?

8 A. Yes.

9 Q. Let's take those one at a time. In the case of  
10 HRT, are you familiar generally with clinical studies  
11 that showed about a 1.2 relative risk?

12 A. Yes.

13 Q. Help us understand how a relative risk that low  
14 could have supported a causal inference or causal  
15 association when it comes to HRT?

16 A. That story comes from first observational  
17 studies but was confirmed in randomized control  
18 trials. So when you find a small risk that you are  
19 looking for in a randomized control trial, that's a  
20 different circumstance for one. So that's really the  
21 best study design to confirm causation, and that's why  
22 there is confidence in that because of the study  
23 design.

24 Q. Why is a randomized control trial a better study  
25 design if you can do it?

1 A. Assuming it is properly done, it has the  
2 advantage of assigning people to the exposure as  
3 opposed to them finding their way to the exposure on  
4 their own. So it takes away the possibility somebody  
5 is different and, therefore, having exposure. This  
6 way you control for that. And it also helps to  
7 minimize, not eliminate, but minimize confounding, and  
8 it helps to minimize confounding of both known and  
9 unknown confounders, which is really important.

10 Q. We will talk a little bit about confounding in a  
11 moment.

12 But as a practicing pulmonologist, are you  
13 Dr. Diette, also familiar with the epidemiology  
14 regarding secondhand smoke?

15 A. Yes, generally, yes.

16 Q. Yesterday secondhand smoke was raised as an  
17 example of an area of epi with a low or weak relative  
18 risk that, nonetheless, has been found causal. Can  
19 you help us explain that?

20 A. Yes. The starting point for that was knowing  
21 already that tobacco smoke causes lung cancer. This  
22 was done in an era where the biologic plausibility or  
23 even certainty was well-established, and the authors  
24 of at least one of the studies that's been cited where  
25 they looked at passive smoke in homes said that was so

1 strong that's why they could interpret a 1.2 as being  
2 causal along with many other things where they found  
3 dose-response to be convincing, and many other  
4 Bradford Hill criteria.

5 So, as an example, where you still go through  
6 the Bradford Hill criteria, and you can arrive at a  
7 conclusion of causation, just like you can go through  
8 the criteria and not arrive at a causal conclusion.

9 Q. In terms of your review of the talc and ovarian  
10 cancer epidemiology, do you find it to be analogous to  
11 the epidemiology of secondhand smoke and lung cancer?

12 A. No, it is not.

13 Q. Dr. Diette, we were speaking a minute ago about  
14 some of the weak or low relative risks that were found  
15 in some of the case-control studies. Correct?

16 A. That's right.

17 Q. Can you help us understand how, in terms of a  
18 body of epidemiology literature, a case-control study  
19 fits?

20 A. It is a good study design. It is one of the two  
21 main observational study designs with case-control and  
22 cohort being the two. You can use them in different  
23 circumstances and you can talk about strengths and  
24 weaknesses, but Leon Gordis, who was one of my  
25 teachers, this is in addition to his book, he

1 describes case-control studies coming after somebody  
2 has made an observation or has the idea there might be  
3 some signal, and then says that the next step to  
4 elucidate the relationship is to do a cohort study to  
5 help confirm it, and gives a good example of where for  
6 a while people thought high fat diet increased the  
7 risk of breast cancer because there was a signal from  
8 case-control studies, and I think the odds ratio was  
9 about 1.6, but cohort studies were done and showed  
10 that wasn't the case, and now that issue has gone away  
11 because of that sequence. So this is one way they  
12 conceptualize. They have some similarities, but often  
13 they are done in sequence.

14 Q. In terms of the weak or low association seen in  
15 some of the talc and ovarian cancer literature, is  
16 that confined to the case-control studies?

17 A. It is.

18 Q. Tell us, were cohort --

19 THE COURT: I want to go back. I want to  
20 follow up on the question, the previous area where he  
21 answered the question.

22 You asked a question: In terms of your review  
23 of the talc and ovarian cancer epidemiology, do you  
24 find it to be analogous to the epidemiology of  
25 secondhand smoke and lung cancer? He said: No, it is

1 not. I want him to summarize why he does not.

2 Can you answer that question for me?

3 THE WITNESS: Absolutely.

4 Just to be clear, the starting point for both  
5 of those is a weak relative risk; and in both cases,  
6 investigators would be appropriately concerned that  
7 they may have found something that isn't causal, and  
8 they would be very worried especially because it is a  
9 weak risk about the potential for confounders and for  
10 bias and other issues.

11 In tobacco smoke, these studies were done so  
12 well into the general knowledge about tobacco smoke  
13 and lung cancer that that was no longer a question.  
14 Nobody --

15 THE COURT: I heard your answer to that. Now,  
16 we're going to move to your review of the talc study  
17 and why you don't find it analogous.

18 THE WITNESS: I have not seen anybody express  
19 that there is a body of evidence for talc as a  
20 carcinogen where that is already so well established  
21 where you would take any finding and say that is  
22 causal.

23 To go on, though, they also cited good  
24 consistent dose-response findings in the secondhand  
25 smoke study, and you will see later, but that is not



1 what I believe is shown in the ovarian cancer  
2 literature. I think consistency was found there, and  
3 it's not found here.

4 So it wasn't just one Bradford Hill criterion,  
5 and the way those authors summarize in their final  
6 paragraph is, they say there is an abundance of  
7 Bradford Hill criteria that are satisfied, and,  
8 therefore, that's why you should accept the small  
9 relative risk. I don't think there is that abundance  
10 for talc and ovarian cancer.

11 THE COURT: Okay. Thank you.

12 BY MS. BROWN:

13 Q. Just to sort of close the loop on what Her Honor  
14 was asking about, was there also a proven or  
15 understood biologically plausible mechanism by which  
16 cigarette smoke can cause lung cancer?

17 A. That was the point. That was well enough worked  
18 out in primary smokers that they were able to  
19 extrapolate that because it is basically the same  
20 smoke.

21 Q. In terms of how that relates to the talc  
22 epidemiology, in your review of the data, has there  
23 been a proven biological mechanism by which talc can  
24 cause ovarian cancer?

25 A. I have not been able to identify it. And I

1 noticed the authors of the epidemiologic papers also  
2 point to that as being not established.

3 Q. Doctor, we spoke a little bit about some of the  
4 case-controls weak or inconsistent, small, relative  
5 risk. What do the cohorts or the prospective studies  
6 conclude on that score?

7 A. For Gonzalez, they say, "douching, but not talc  
8 use, was associated with increased risk.

9 Houghton: "Based on our results, perineal  
10 powder use does not appear to influence ovarian cancer  
11 risk."

12 And Gertig: "Our results provide little  
13 support for any substantial association between  
14 perineal talc use and ovarian cancer risk overall."  
15 And we know that was updated in the Gates study, which  
16 doesn't change that conclusion.

17 MS. BROWN: For the record, we will note the  
18 Gonzalez study is at A 47; the Houghton study is at A  
19 65; and the Gertig study is at A 45.

20 Q. Dr. Diette, to round out our discussion of the  
21 strength of association, can you summarize your  
22 opinion based on your review of the totality of the  
23 evidence as to whether properly applying the Bradford  
24 Hill criteria would allow you to conclude that there  
25 is a strong association between talc use and ovarian

1 cancer?

2 A. I think you have to conclude that it is weak.  
3 One is the target. It is almost impossible to have a  
4 study land on 1.0. When you get close to 1, you are  
5 really getting remarkably low. It doesn't mean it  
6 can't be causal, but it makes you more concerned than  
7 if it is a larger one.

8 One of the things we didn't show on the slide  
9 for Bradford Hill is they gave an example for a  
10 low-risk, which he said was about twofold or a little  
11 less. 2-plus, I think most of my colleagues would  
12 call a medium or high risk. But in the ones,  
13 especially, in the low ones, that is objectively weak.  
14 That only comes from one study design, from the cohort  
15 studies, if you pool it, there is no elevated risk.

16 Q. Can you help us understand, first of all, when  
17 you are dealing with a low or weak relative risk like  
18 1.2 or 1.3, are there challenges to determining  
19 causation in that context?

20 A. There are. This is a list of three of them.  
21 They are not only a challenge when you have a low  
22 estimated risk, but they are especially important when  
23 you have a low risk because they are very susceptible  
24 to distortion by these factors whereas a large  
25 estimated risk which has less chance of being

1 distorted, not no chance, but less chance.

2 Q. We'll talk a little bit about what that means.  
3 But in terms of identifying potential challenges to  
4 interpreting a low or weak relative risk, did IARC  
5 review this data and reach some similar conclusions?

6 A. They did. You will see at the bottom of that  
7 slide they said "chance, bias or confounding could not  
8 be ruled out with reasonable confidence." They raised  
9 the big three issues we grapple with in general.

10 Q. Give us an understanding, what does it mean that  
11 the chance or bias or confounding could be distorting  
12 a small relative risk like a 1.2 or a 1.3?

13 A. Chance is typically handled well by statistical  
14 testing, but there is always a chance every time you  
15 do a study, literally, you can get the wrong answer.  
16 You are literally taking a chance reaching the wrong  
17 conclusion. That happens.

18 Bias is a systematic factor that distorts the  
19 findings. It can drag the risk up or down depending  
20 upon which way it works.

21 Confounding are factors that are associated  
22 with the exposure that are the real cause rather than  
23 the thing you are studying.

24 Q. Is the concern about bias, confounding and  
25 chance heightened in a case where you don't have a

1 strong association?

2 A. Absolutely. A low association is very  
3 vulnerable to all three of those.

4 Q. I want to talk to you about bias and  
5 confounding.

6 Did you review the Penninkilampi study at  
7 A 109 as part of your work here?

8 A. I did.

9 Q. Does Penninkilampi comment on something called  
10 "recall bias"?

11 A. Yes.

12 Q. Tell us first what Penninkilampi says and help  
13 us understand what that means, if you could,  
14 Dr. Diette.

15 A. In this particular citation he says that "a  
16 limitation of the study is that it pools nonrandomized  
17 studies, primarily case-control studies, and that the  
18 retrospective nature of case-control studies  
19 introduces the potential for recall bias. In this  
20 case it's entirely possible that patients with ovarian  
21 cancer may be more aware of their previous talc use  
22 and hence may be more likely to report higher past  
23 use."

24 This is a 2018 opinion from an author after  
25 having performed a meta-analysis.

1 Q. And so explain to us -- I know we're going to  
2 look at an example in a minute. Explain to, in  
3 practice, what does "recall bias" mean, how does it  
4 work, and how does it happen?

5 A. There is a broader heading, which is an  
6 "information bias." Information bias is when the  
7 information that you get from your two groups -- in  
8 this case, the cases with the disease and the controls  
9 without disease. It's different information. And if  
10 it is systematically different that creates a bias.  
11 And that can come because of recall, not that you  
12 don't remember well, but you remember selectively.  
13 You have a different memory because you are sick and  
14 because you have an illness.

15 Q. Just to interrupt you there, Doctor, is it more  
16 likely when someone has been diagnosed with a disease  
17 and asked questions about habits or use of a product,  
18 are you more likely to remember you might have used it  
19 or something like that?

20 A. That's the notion. A classic example is a woman  
21 who gives birth to a child with a birth defect will  
22 rack their brain trying to think what might have  
23 happened during pregnancy, which is a very different  
24 experience than somebody who gave birth to a child  
25 without a birth defect where she may not have thought

1 about those issues at all.

2 Q. Dr. Diette, did you review the Schildkraut 2016  
3 paper at A 129 as part of your work here?

4 A. Yes.

5 Q. Does the Schildkraut paper inform your opinion  
6 about the potential for recall bias in the talc  
7 ovarian cancer epidemiology?

8 A. It is amazing.

9 Q. Tell us what is amazing about this particular  
10 study.

11 A. A few things.

12 One is that we talk about recall bias more  
13 than we actually assess it. All my colleagues I know  
14 of are concerned about the potential for it in any  
15 case-control study. This is a rare example where  
16 these authors sought to demonstrate it, and they did  
17 demonstrate it, and they had a rationale where they  
18 believed because of lawsuits, that might have  
19 heightened awareness of talcum powder use, especially  
20 among women with ovarian cancer. So they chose 2014  
21 as a date that happened in the midst of their study,  
22 and they thought 2014 would mark a line where women  
23 would suddenly become aware of the news about  
24 lawsuits.

25 Q. Did their study contain information where they

1 sought out to test whether or not that was true?

2 A. Yes.

3 Q. Tell us, if you could, did you put together a  
4 graph to help us understand what they did?

5 A. I did.

6 Q. I can give you the pointer if helpful.

7 A. I don't need it.

8 Q. Can you help us understand what they did in the  
9 Schildkraut article and how, if at all, that speaks to  
10 this idea of recall bias?

11 A. This comes directly from the study itself. On  
12 the vertical axis is the percentage of women who  
13 reported using genital talcum powder, and then cases  
14 are in the yellow/gold color, and controls are in the  
15 blue.

16 The left two bars are before 2014 and the  
17 right two bars are after 2014.

18 There are a few things to observe here. One  
19 is before 2014, it was actually a very similar  
20 proportion of women who reported talcum powder use,  
21 and what's up above is a calculated relative risk  
22 which is 1.19 and not significant before that date.

23 Q. Just to go back to our cheat sheet here, we have  
24 a relative risk of 1.19 and we have a confidence  
25 interval crossing 1. Right?



1 A. Yes.

2 Q. To find it on your chart here, how would that  
3 finding be interpreted?

4 A. You interpret that finding as no association.

5 Q. All right. Go ahead.

6 A. And then after 2014, there was an abrupt change  
7 in the reporting of cases. So it went from a little  
8 over a third to a little over half of women now saying  
9 that they had used talcum powder, if they happened to  
10 have ovarian cancer. And you will see the rate of  
11 that in the controls was basically identical to what  
12 it had been. It is a really dramatic effect all of a  
13 sudden pre-and post-2014. And these authors are the  
14 ones who chose that based on what they thought about.

15 The relative risk in that period is almost 3.  
16 It's 2.91, and it is statistical significant. Their  
17 positive finding is confined to post 2014, and they  
18 have a test I've highlighted down below. It is a  
19 statistical test that tells whether or not there is an  
20 effect of that change in the years, and by the  
21 statistical test they have done they say it is  
22 statistically significant with a P of .005.

23 Q. Before I ask you what that tell us, Dr. Diette,  
24 if I understand you, the number of people who did not  
25 have ovarian cancer who reported talc use before 2014

1 and after 2014, how would you compare those?

2 A. The talc use --

3 Q. Before and after, was it different? Was it the  
4 same?

5 A. For the controls it was essentially the same.  
6 For the cases it was dramatically different all of a  
7 sudden.

8 Q. What does that tell you as it relates to this  
9 concept of recall bias that we have been discussing?

10 A. It's extraordinarily consistent with it. This  
11 now goes into my teaching files. The authors have  
12 done a careful job of explaining why they looked for  
13 it, and they found exactly what they were looking for,  
14 and it is a differential effect in cases. So people  
15 who have the disease who change their reporting  
16 abruptly, it's highly consistent with that.

17 Q. Before we close out recall bias, in terms of  
18 when you are looking at a relative risk of 1.2, 1.3,  
19 what does something like that suggest could be doing  
20 to that number? How does that work out in real life?

21 A. This is recall and recall related to lawsuits.  
22 It also could illustrate the same effect that could be  
23 happening for recall for other reasons or reporting  
24 differences.

25 Women and people in general report about

1 sensitive topics differently. It illustrates the idea  
2 there could be a reporting difference in people based  
3 on something about them.

4 Q. What does it suggest in terms of a positive  
5 association? Does that suggest to you that that  
6 association is true or real or something else?

7 A. It is only true after 2014 in this study, and it  
8 is really -- we have seen there's various entities and  
9 authors who have worried about the potential for  
10 recall bias. This proves it's real in at least one of  
11 the studies.

12 Q. One of the other things that was indicated in  
13 the IARC assessment of this epidemiology was something  
14 called "confounding." Is that right?

15 A. That's right.

16 Q. Can you explain to us what that is and why we  
17 have a beer bottle and a cigarette?

18 A. Yes. Confounding refers to a factor which is  
19 associated with the exposure itself that also is a  
20 cause of the outcome you are looking at, and it  
21 matters whether you can account for it or not.

22 So the example I have here is made up. If you  
23 were to do a study of a beer drinker and lung cancer,  
24 you may well find there is a positive risk. We don't  
25 believe beer causes lung cancer, and we know some

1 people go to bars and drink and smoke at the same  
2 time. So you want to account for the smoking. The  
3 smoking would be the confounder. That's the real  
4 cause of the lung cancer.

5 Q. How has this idea of confounding been addressed  
6 or captured in the talc ovarian cancer epidemiology?

7 A. Confounding has been handled in almost every  
8 single study to a certain degree. There's about five  
9 or six that I think one of the meta-analyses  
10 identified as being uniformly or almost uniformly  
11 accounted for, but there are many that are potentially  
12 important that aren't accounted for in most of the  
13 studies.

14 MR. TISI: Objection, your Honor. His expert  
15 report does not talk about any other factor other than  
16 douching. It does not talk about family history,  
17 socioeconomic status, hormone therapy, family history  
18 of breast cancer. It only talks about douching as a  
19 confounding factor, and that's what we're prepared to  
20 discuss with him today.

21 MS. BROWN: Two things on that, your Honor.  
22 Certainly he is speaking about the confounding factors  
23 that were addressed in the talc ovarian epidemiology  
24 which had been fully disclosed and counsel had the  
25 opportunity to question Dr. Diette about. There was

1 also a discussion about potential confounding factors  
2 at his deposition. This is entirely consistent and  
3 based on the very literature that was disclosed.

4 THE COURT: At his deposition where there was  
5 a discussion about confounding factors, were these  
6 other items mentioned?

7 MS. BROWN: I believe so, your Honor. We will  
8 check right now.

9 MR. TISI: If they were mentioned, they were  
10 mentioned in passing.

11 MS. BROWN: To help the Court and move this  
12 along, I will right now confine the discussion to  
13 douching.

14 MR. TISI: Douching was discussed in his  
15 report.

16 THE COURT: She's agreed, and everyone can  
17 look back at the deposition and confirm as well if it  
18 was discussed.

19 BY MS. BROWN:

20 Q. Dr. Diette, confining yourself then just right  
21 now to the potential confounding factor of douching,  
22 can you help us understand how that plays out in the  
23 talc/ovarian cancer epidemiology?

24 A. Definitely. We know about the Gonzalez study.

25 Q. What were the findings of that and how does it

1 relate to this issue?

2 A. The Gonzalez study examined douching and talc  
3 use as a potential risk factor, and they found that  
4 douching was positively associated with ovarian  
5 cancer, and they found talc was not. They found that  
6 the two habits were associated with each other. So  
7 that women who douched also tended to use talc, and  
8 vice versa. So there was a strong relationship  
9 between the two.

10 Although that study found a risk for talc,  
11 that was less than 1 in that study, they still  
12 concluded the douching might turn out to be important.  
13 They gave reasons for it in terms of some potential  
14 plausible reasons, and they also said if the earlier  
15 studies had not accounted for that they may have  
16 missed an important confounding factor.

17 Q. Based on your review of the talc and ovarian  
18 cancer epidemiology, were there a set of consistent  
19 potential confounders that were addressed in those  
20 studies?

21 A. It wasn't consistent. It varied from study to  
22 study. Even the accounting for confounders wasn't  
23 uniform. So even if someone was going after the same  
24 basic concept, they didn't necessarily use the same  
25 indicator or the same measure of that particular

1 confounder.

2 Q. What's the significance of a potentially  
3 inconsistent controlling for confounders in a body of  
4 epidemiology like this with a low to weak to  
5 inconsistent relative risk?

6 A. It matters a lot, and it matters for a couple of  
7 reasons. One is because confounding factors have a  
8 much greater potential to distort the findings with a  
9 low risk, and that is especially true in something  
10 where the majority of cases of ovarian cancer don't  
11 have a known risk.

12 So most occur without a known high risk. So  
13 most of the potential confounding is not known. And,  
14 so, there are really two reasons why this becomes very  
15 important in this particular matter.

16 Q. Dr. Diette, before we move on to a discussion of  
17 dose-response, I wanted to ask you one more question  
18 on recall bias. We were addressing that in the  
19 context of the Schildkraut study, do you remember  
20 that?

21 A. Yes.

22 Q. There the inquiry was whether an individual was  
23 reporting talc use pre-and-post lawsuit media  
24 attention in 2014. Do you recall that?

25 A. I do.

1 Q. Is recall bias something that could exist in the  
2 epidemiology separate and apart from the 2014 media  
3 attention on talc and ovarian cancer?

4 A. Yes, of course.

5 Q. Can you explain that to us, please?

6 A. I would broaden that to say information bias.  
7 We're talking about case-control studies, for example,  
8 where the signal is found, right? And in every study  
9 where I could find whether it was acknowledged or not,  
10 there were interviewers who administered the surveys.

11 Another form of bias introduced by  
12 interviewers who know the status of somebody's disease  
13 at the time they interviewed them. So it's another  
14 way to change what the information is that comes out  
15 by probing more thoroughly when you know somebody has  
16 cancer. So the information bias as a general term  
17 could be quite different and recall bias can occur on  
18 its own without any media reports.

19 Q. Were most of the case-control studies conducted  
20 through that interview process you just discussed with  
21 us?

22 A. A majority were. I don't know I can find for  
23 sure they mentioned that as a method in every one, but  
24 for the most part it was interview administered.

25 Q. We heard some discussion yesterday from



1 Dr. McTiernan about the survey process by which  
2 members of the cohort studies were asked about their  
3 habits. Were you here for that, Dr. Diette?

4 A. Yes.

5 Q. Tell us about how the survey process could or  
6 could not affect the reliability in the cohort  
7 studies.

8 A. One thing I would say, self-administered surveys  
9 are not a feature of cohort studies. They were in  
10 these cohort studies, but they are not a feature.  
11 Either of these studies designs could use  
12 self-administered or interview administered or both in  
13 the study.

14 Because we are talking about a sensitive topic  
15 for some people, some women may be less forthcoming  
16 about personal hygiene habits and I would say that is  
17 especially acknowledged that issue in controls in  
18 general, I'm not talking about just in this matter,  
19 who have less at stake in that study, may be less  
20 forthcoming about what their personal habits are. So  
21 with an interviewer there face-to-face, there is a  
22 little bit of loss of privacy, so that can also induce  
23 a little bit of a change as well.

24 Q. I want to talk a little bit about dose-response.  
25 Was this part of your review of the talc epidemiology?

1 Did you consider the Bradford Hill criteria of  
2 dose-response?

3 A. I did.

4 Q. Give us an understanding what your opinion is as  
5 to whether the talc epidemiology shows a  
6 dose-response.

7 A. There is a lot of information to consider. One  
8 is that none of the cohort studies -- none of the  
9 prospective cohort studies showed a dose-response.  
10 Where there were case-control studies that had some  
11 estimate of dose-response, the results were highly  
12 variable. So there were a few that purported to show  
13 a positive dose-response. There were also some that  
14 showed a negative dose-response, meaning the more you  
15 used, the lower your risk.

16 There is an example in my report of basically  
17 a horizontal dose-response meaning there is no change  
18 up or down no matter what your dose was.

19 Then we have some examples of some really  
20 bizarre relationships. So these are just three  
21 specific studies. I'll say it is Cook, Mills and  
22 Rosenblatt.

23 MS. BROWN: For the record, Cook is at A 21;  
24 Mills is at A 94; and Rosenblatt is at A 125.

25 Q. Help us to understand, if you could, what we are

1 looking at in terms of these three exemplar studies  
2 found when it comes to dose-response.

3 A. To be clear, each of these is using a different  
4 scale. But from left to right on each one, you go  
5 from lower amount to higher amount of exposure. What  
6 you might expect to see is that in the lower left of  
7 each one of those figures it would be the lowest  
8 point; and the upper right would be the highest point,  
9 if there is a positive dose-response. If it is  
10 negative, it might go from upper left all the way down  
11 to the lower right.

12 But here there are things that don't make any  
13 sense to me biologically, like why the third category  
14 would have the lowest risk on the Cook one, and why  
15 the first and fourth categories would have the same  
16 risk. These are just examples. But in the context of  
17 there being both positive, negative, no, and  
18 haphazard, it is really a mess. It is all over the  
19 place, and it is not very reassuring that a  
20 dose-response relationship has been established.

21 Q. Is a dose-response relationship required for a  
22 causal association?

23 A. Not required, but it is one important criterion.

24 Q. How did these findings as you described them to  
25 us on inconsistent or variable dose-responses in the

1 talc epidemiology inform your opinion in this case?

2 A. I saw them as highly inconsistent, and it made  
3 me very worried about whether or not the investigators  
4 had measured properly what they had hoped to, or that  
5 there is in fact no causal relationship, and this is  
6 just what happens when you don't have a causal  
7 relationship.

8 Q. Did some of the studies themselves comment on  
9 whether or not the authors, having conducted their own  
10 study, found or did not find a dose-response?

11 A. Yes.

12 Q. Would you highlight some of those for the Court,  
13 and we will also read the exhibit number.

14 A. For a shorter one, the Health Canada from 2018,  
15 there is a lack of an available exposure effect  
16 relationship in the human epidemiologic data.

17 Q. For the record, Health Canada is A 58.

18 A. Houghton, this corroborates our results, there  
19 was no statistically significant risk with increasing  
20 duration of perineal powder use.

21 Q. At A 65.

22 How do these findings inform your opinion,  
23 Dr. Diette?

24 A. I think the authors of various studies are  
25 pointing this out because it is important, and one

1 would expect to see a dose-response. As you said, it  
2 is not required, but you would expect to see one for  
3 an exposure that's causing a disease.

4 Q. The final category as it relates to the Bradford  
5 Hill analysis that I want to discuss with you is  
6 consistency.

7 Can you tell us, No. 1, did you find  
8 consistency in your review of the body of literature  
9 related to talc and ovarian cancer?

10 A. I didn't. That's an important question because  
11 you said the body of the evidence. So this is not an  
12 exercise of just trying to find consistency here and  
13 there, or a couple of examples of a couple of things  
14 that happened to agree, but really looking at the  
15 total information you have available.

16 Q. And so explain to us: Did you attempt to  
17 evaluate whether there was consistency in a number of  
18 different areas that touch this area of scientific  
19 inquiry?

20 A. Yes.

21 Q. Let's start with study design. Tell us what  
22 your inquiry was there and what it showed?

23 A. Basically, the weak signal comes from  
24 case-control studies only, and that there is not a  
25 signal from cohort. So when you do the retrospective

1 studies you have a weak signal; and when you do the  
2 prospective studies, you have no signal, and that's  
3 inconsistent by study design. The different study  
4 designs produce a different result.

5 Q. You next have listed "condom and diaphragms."  
6 Tell us what you are referring to here and how that  
7 informs your analysis.

8 A. Since the general notion here is about perineal  
9 application of talc and whether it migrates to the  
10 ovaries and then causes some harm, many but not all  
11 investigators looked at some other ways to get talc up  
12 towards the ovaries, so in this case things that would  
13 go directly into the vagina. And so condoms and  
14 diaphragms we're looking at, and for the most part  
15 were either less than 1, but there was not a  
16 consistent signal that there was harm or a positive  
17 risk from these. So that was inconsistent with the  
18 notion that talc in the genital tract would lead to  
19 ovarian cancer.

20 Q. And dose-response we just discussed. Right,  
21 Dr. Diette?

22 A. Yes.

23 Q. Did you find those findings to be consistent or  
24 inconsistent?

25 A. Inconsistent, as we just showed.

1 Q. On your list you have tubal ligation. Tell us  
2 what that is and how that informs your assessment of  
3 consistency here.

4 A. Many investigators considered if you interrupted  
5 the female reproductive tract, you would block the  
6 pathway from the perineum to the ovaries. So by tubal  
7 ligation, you are cutting off the route through the  
8 Fallopian tubes. If the idea was correct, that  
9 perineal talc migrates, this ought to interrupt that  
10 exposure to the ovaries, and there were inconsistent  
11 findings. There were some positive, some negative,  
12 but not consistent.

13 Q. What you are saying, Doctor, is if the proposed  
14 biological mechanism or exposure pathway by which talc  
15 gets to the ovaries is migration, if a woman has a  
16 tubal ligation, that would prevent a particle from  
17 traveling through the Fallopian tubes to the ovaries,  
18 if this theory were true, you would expect to see a  
19 decreased risk in women who had tubal ligation. Is  
20 that right?

21 A. Yes, inconsistently. So some studies showed it  
22 and some did not.

23 Q. Finally, Dr. Diette, you have NSAIDS on the  
24 list. Tell us how that informed your determination  
25 about whether or not the consistency factor of

1     Bradford Hill was met here?

2     A.     There were several studies that considered -- or  
3     were conceptualized as anti-inflammatory drugs, and  
4     there were a mixture of findings. So some positive,  
5     some negative, including the study that we looked at  
6     first, which actually had a positive risk for NSAIDS  
7     use, meaning that there was higher risk of ovarian  
8     cancer, which is inconsistent with the idea that  
9     NSAIDS would be protective against ovarian cancer.

10    Q.     I want to show you something Dr. McTiernan used  
11    yesterday, which is this forest plot. Have you seen  
12    something similar to this in some of the scientific  
13    papers?

14    A.     Yes.

15    Q.     One of the things you'll recall from  
16    Dr. McTiernan's testimony is that she suggested that  
17    the findings of these epidemiology studies show  
18    consistency. Were you here for that?

19    A.     Yes.

20    Q.     In your view is that correct, Dr. Diette?

21    A.     It is not. I think especially if we look down  
22    at the cohort studies, there is something that for me  
23    at least is a little misleading there which is to show  
24    Gertig, Gates and Gates all in a row because it's  
25    basically one study. So it makes it look as if



1 there's five studies.

2 If we look at the most recent one, which is  
3 the 2010, that box is a little to the right of 1; the  
4 Houghton study is a little to the right of 1; and  
5 Gonzalez is to the left. I don't find that to be  
6 consistent within the cohort studies.

7 Q. What about the suggestion, Well, a whole bunch  
8 of these studies have some point estimate around 1.2;  
9 therefore, this entire body of epi is consistent. How  
10 do you interpret this body of literature?

11 A. A couple of things. It is not fully consistent  
12 even if you summarize the risk for the case-control  
13 studies. But it is also compatible with what many  
14 investigators are worried about, which is risk of bias  
15 and confounding, which is you would expect to see it  
16 driving the same direction. So this wouldn't be a  
17 surprise if you had, for example, recall bias or  
18 confounding driving it a little bit to the right.

19 Q. If we could go back to the PowerPoint a couple  
20 of more areas I want to finish up with you,  
21 Dr. Diette.

22 As it relates to study design, did some of the  
23 meta-analyses like Berge 2018 comment on whether what  
24 they were finding in case-controls versus cohorts were  
25 consistent or not?

1 A. Yes.

2 Q. Is Berge A-11 -- tell us what those authors  
3 concluded on that score?

4 A. This points to one of the points we were making  
5 on the prior slide. Several aspects of our results,  
6 including the heterogeneity of results between case  
7 control and cohort studies, however, do not support a  
8 causal interpretation of the association.

9 Q. Did you consider what the authors themselves  
10 found on the consistency score when it came to doing  
11 your Bradford Hill analysis? For example, what the  
12 Berge authors concluded here.

13 A. Oh, yes. This is the same concept I'm talking  
14 about.

15 Q. On this point, Dr. Diette, as we talked about  
16 with strength of association, in your opinion, could  
17 you properly apply a Bradford Hill analysis to this  
18 epidemiology and conclude that the findings are  
19 consistent?

20 A. No.

21 Q. Give us just a brief explanation of why that is.

22 A. Because I think consistency is a global issue,  
23 and just finding consistency between a couple of  
24 studies is not enough. These are broad categories of  
25 inconsistency. So when the study design helps to

1 determine what the result is, that's a big  
2 inconsistency. When dose-response is all over the  
3 map, that's an inconsistency. These are examples of  
4 things where I don't think you can pool all of the  
5 information that's available and say that is a  
6 consistent finding.

7 Q. Two quick areas before we conclude here this  
8 morning.

9 You mentioned earlier a part of your  
10 methodology included looking at organizations and  
11 public health authorities like IARC that have reviewed  
12 the talc epidemiology. Is that right?

13 A. That's right.

14 Q. There was a suggestion yesterday that talc may  
15 contain asbestos. Did you hear that from  
16 Dr. McTiernan?

17 A. I did.

18 Q. Did IARC conduct some epidemiology studies that  
19 you reviewed as part of your work in this case that  
20 informed your opinion on that score?

21 A. They didn't conduct it, but they highlighted  
22 studies they thought would be most informative for  
23 that issue.

24 Q. Explain to us what those studies were and how  
25 they informed your opinion.

1 A. They pointed toward studies of miners and  
2 millers of the source of talc with the idea being  
3 these would be workers who would have really quite  
4 high exposures, and they said because of that, that  
5 would be a good place to look for cancer, if it was in  
6 fact a carcinogen.

7 Q. Did those studies of the talc miners and  
8 millers, did they investigate whether those folks were  
9 getting traditionally asbestos-related diseases like  
10 mesothelioma?

11 A. They did.

12 Q. What were the findings?

13 A. No mesothelioma in these studies from Vermont  
14 and Italy and Austria and France.

15 Q. Was this data included in IARC's review of the  
16 cosmetic talc epidemiology?

17 A. It was.

18 Q. And did this inform in part IARC's determination  
19 as it relates to the talc epidemiology recall chance  
20 and bias could not be ruled out?

21 A. It was one of their conclusions, but this  
22 informed their opinion that talc at least from these  
23 sources was not a carcinogen.

24 Q. Dr. Diette, did IARC also look at data regarding  
25 something called talc pleurodesis that Dr. McTiernan

1 discussed yesterday?

2 A. Yes.

3 Q. As a pulmonologist, have you instructed others  
4 to perform talc pleurodesis or performed it yourself?

5 A. I have done both.

6 Q. Give us a little understanding of what the  
7 procedure is.

8 A. Sure. This picture represents a couple but not  
9 only the forms that we get it in. What we get is  
10 talcum powder in order to put it into the space  
11 between the chest wall and the lung. We do it by  
12 making a small incision in the chest wall and  
13 basically squirt it in there and leave it in there  
14 long enough for it to have the therapeutic effect we  
15 are looking for.

16 Q. As it relates to whether or not this procedure  
17 has caused cancer in individuals who have undergone  
18 it, have you reviewed IARC's review of the literature  
19 on that?

20 A. I've looked at IARC, and also since then I've  
21 looked for anything newer.

22 Q. Tell us what the findings are as it relates to  
23 whether or not injecting talc into the pleural space  
24 causes cancer.

25 A. It does not appear to cause cancer.

1 Q. Have folks who have undergone talc pleurodesis  
2 been followed for decades to investigate that point?

3 A. There are a few studies that have looked for  
4 decades, and there is a whole variety of case series  
5 and case reports as well.

6 Q. Dr. Diette, could you then finally summarize for  
7 us your opinion and review of the totality of the  
8 evidence as it relates to what we asked you to do  
9 here, investigate the hypothesized connection between  
10 talc and ovarian cancer?

11 A. The only signal I see is the pooled relative  
12 risk from certain of the case-control studies and  
13 otherwise -- which provides a weak association. From  
14 the cohort studies we get no association. And I think  
15 the other Bradford Hill criteria have serious issues  
16 with them that don't support there being a causal link  
17 between perineal talcum powder and ovarian cancer.

18 Q. In your view, could a scientist properly apply  
19 the Bradford Hill criteria to the talc epidemiology  
20 and conclude that there is a causal association  
21 between talc and ovarian cancer?

22 A. It doesn't make sense to me.

23 MS. BROWN: Thank you very much for your time,  
24 Dr. Diette.

25 Unless your Honor has an area of inquiry, I'm

1 all done.

2 THE COURT: I think they have something for  
3 you.

4 MS. BROWN: On the objection that counsel made  
5 to the socioeconomic status, it is actually disclosed  
6 as an opinion in his report at page 21.

7 THE COURT: I saw it. I think that was the  
8 only one, and I did see it is in his report. That was  
9 on the confounding factors.

10 MS. BROWN: Thank you.

11 THE COURT: I did not see anything else on it.  
12 You did not want to follow up on that to confirm that.

13 MS. BROWN: I'll do it real quick.

14 BY MS. BROWN:

15 Q. Dr. Diette, just to revisit this idea of  
16 potential unknown or uncontrolled for confounders, we  
17 had on the slide socioeconomic status. Can you help  
18 us understand what that means and how it relates to  
19 the talc epi?

20 A. Sure. There is a paper by Alberg that I cited  
21 which points to low socioeconomic status being a risk  
22 factor for ovarian cancer. That's typical of many  
23 kinds of illnesses in the United States, that lower  
24 socioeconomic status confers a risk for all sorts of  
25 diseases. What's hard about that is that low

1 socioeconomic status is a complex phenomenon; it  
2 could mean low income; it could mean low education; it  
3 could mean different food, different jobs, different  
4 places where you live -- all sorts of different things  
5 that all sort of coalesce together to make somebody  
6 have a higher risk.

7 In most of the studies I saw there was not  
8 measurement of socioeconomic status, and where there  
9 was there was a crude indicator. It might have been  
10 education, which is a proxy for it, but it really  
11 doesn't fully capture everything about socioeconomic  
12 status. So that's one more important potential  
13 confounder that is undercovered in these studies.

14 Q. The final question, Dr. Diette, is how does that  
15 relate -- and when we are dealing with a disease like  
16 ovarian cancer, how important is something like a  
17 confounder like socioeconomic status that may not have  
18 been controlled for in some of the studies?

19 A. It is one more thing that would be missing from  
20 the question, especially with a low or weak risk that  
21 will distort the findings.

22 MS. BROWN: Thank you, your Honor.

23 THE COURT: We'll take a break now before we  
24 start the cross. It was an hour and a half. So  
25 you've got three hours.



1           We're going to take a break. So you can step  
2 down.

3           THE DEPUTY CLERK: All rise.

4           (Recess.)

5           (Continued on the next page.)

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **GREGORY B. DIETTE**, resumed.

5 CROSS-EXAMINATION

6 BY MR. TISI:

7 Q. Good morning, Dr. Diette.

8 We met at your deposition. Good to see you  
9 again. I kind of had a plan I was going to go at, but  
10 I'm going to tackle first things first.

11 A. Okay.

12 Q. The first epidemiology study that addressed the  
13 issue of ovarian cancer and talcum powder products was  
14 1982. Correct?

15 A. That's my understanding.

16 Q. There has been about 40 years of research since  
17 then?

18 A. Just about.

19 Q. One of the last questions Ms. Brown asked you  
20 was whether or not no reasonable scientist could reach  
21 the conclusion that talcum powder products cause  
22 ovarian cancer in 2019. Is that your testimony?

23 A. It is.

24 Q. Could you please do me a favor and take out the  
25 Penninkilampi study, please. That is Exhibit No. 62

1 in your binder.

2 The Penninkilampi study, if you go to the  
3 conclusion, Ms. Brown asked you to read a sentence out  
4 of it.

5 Let me ask you whether the Penninkilampi study  
6 says the following. This is just to orient us. This  
7 is a meta-analysis. Correct?

8 A. It is.

9 Q. It says:

10 "The results of this review indicate that  
11 perineal talc use is associated with a 24 to  
12 39 percent increased risk of ovarian cancer."

13 Did I read that correctly?

14 A. You did.

15 Q. (Reading.)

16 "While the case-control studies are prone to  
17 recall bias, especially with intense media attention  
18 following commencement of litigation in 2014, the  
19 confirmation of an association in cohort studies  
20 between perineal talc use and serous invasive ovarian  
21 cancer is suggestive of a causal association."

22 Do you see that?

23 A. I do.

24 Q. Is that an incorrect statement?

25 A. There is more than one there. Are we talking

1 about the last statement or everything there? It is  
2 not disputable that the association that they estimate  
3 from this ranges --

4 Q. Doctor, is it suggestive of causal association?

5 A. I'm just clarifying. You read a lot of stuff.  
6 I just want to know what I'm reacting to.

7 Specifically, we are saying --

8 Q. Is it suggestive of a causal association? Is  
9 that what the authors say?

10 MS. BROWN: Your Honor, could he be permitted  
11 to finish his answer?

12 THE COURT: Mr. Tisi, we're just starting.  
13 Let him answer. And he is right, there are several  
14 sentences you read with different ideas in them. So  
15 let him break them down and answer it.

16 BY MR. TISI:

17 Q. I will rephrase the question, if you don't mind.

18 Do the authors conclude that the data they  
19 reviewed in this study is suggestive of a causal  
20 association?

21 A. That particular finding they say is suggestive  
22 of a causal association.

23 Q. If you go to the front page of this in the  
24 conclusions it says:

25 "In general, there is a consistent association

1 between perineal talc use and ovarian cancer."

2 Do they say that?

3 A. They do.

4 Q. You disagree with that?

5 A. Well, I don't know. Within the boundaries of  
6 this paper, for example?

7 Q. This paper reviewed all the studies, did it not?

8 A. No, it didn't. They left out an important one.  
9 But they reviewed many of the studies.

10 Q. Do they also conclude that because there was a  
11 specific association with a particular type of ovarian  
12 cancer that that mitigated against recall bias?

13 A. They did say that. I wasn't done with the one  
14 before.

15 THE COURT: There was no answer to that yet.  
16 He wanted to clarify he meant within the term of this  
17 paper. There wasn't an answer.

18 A. They don't tell what specifically they are using  
19 for it in general. But they did have an estimate that  
20 includes pooling all of the studies together, meaning  
21 the case-controls and the cohort studies. Those when  
22 you pool them together, might support that statement.  
23 If you look at the case-control separately, as they  
24 often did from the cohorts, you get two different  
25 answers to that. So I'm assuming they're talking

1 about if they pooled two heterogeneous groups of  
2 studies, they get an overall finding that way.

3 Q. Did the authors address the issue of  
4 heterogeneity?

5 A. They did.

6 Q. Did they find there was heterogeneity?

7 A. I didn't see a test of heterogeneity for the  
8 study design I don't think. They comment on whether  
9 there is heterogeneity by outcomes.

10 Q. Doctor, you've written a 51-page report.  
11 Correct?

12 A. That sounds about right.

13 Q. This report is dated February 25th of this year?

14 A. I'm sure it is.

15 Yes, it is.

16 Q. The methodology used to analyze the causal  
17 question in this case is the Bradford Hill criteria?

18 A. That's part of the methodology.

19 Q. You agree the Bradford Hill criteria is a  
20 framework that epidemiologists use?

21 A. I do.

22 Q. And you agree, is there any important  
23 epidemiologic study that you considered in your  
24 analysis that you believe the plaintiffs' experts did  
25 not?

1 A. I don't know. I didn't try to make an  
2 accounting of which ones which expert considered and  
3 which ones they didn't. So there are many plaintiffs'  
4 experts here. Right? Are we talking about folks who  
5 focused on epidemiologic studies?

6 Q. Yes.

7 A. I don't recall if there was one that was left  
8 out. I would say that I think each of them  
9 acknowledge the meta-analyses, including the more  
10 recent ones, which I think look like they have a  
11 pretty complete list. So either directly or  
12 indirectly I think they've accounted for the  
13 epidemiologic studies.

14 Q. The Bradford Hill analysis also involved  
15 consideration of biologic evidence as well?

16 A. It does.

17 Q. Can you think of any important biologic study  
18 you considered that any of plaintiffs' experts did not  
19 since you criticized them in your report?

20 A. Could you be specific?

21 Q. Did you identify any? I just want to know if  
22 the world of studies you looked at is exactly the same  
23 for the most part in terms of the major studies that  
24 the plaintiffs' experts looked at.

25 A. I didn't memorize the list of studies they

1 looked at.

2 Q. So you haven't identified any you think was a  
3 major omission that they did not consider that you  
4 did?

5 A. For a biologically relevant study?

6 Q. Right.

7 A. I don't recall any that I saw that they left  
8 out.

9 Q. Now, there were studies you left out. Correct?

10 A. It depends upon what do you mean by "left out"?

11 Q. We received two days ago a supplemental reliance  
12 list --

13 MR. TISI: Can you bring up PSC Diette 2. We  
14 were provided --

15 MS. BROWN: Your Honor, if I may, counsel  
16 objected to this list, and pursuant to that objection  
17 we didn't use any of these studies on direct. So I  
18 would object, if I could, to the use of a list that  
19 per agreement none of those studies were referenced on  
20 direct.

21 MR. TISI: I am not going to use them except  
22 to say they were not part of his initial analysis.

23 THE COURT: Are any of the ones on their list,  
24 studies that were available at the time he wrote his  
25 report? You can ask that. Ask that question.



1 BY MR. TISI:

2 Q. Are there studies on this list that were  
3 available at the time you issued your report?

4 For example, Henderson 1971. Was that  
5 available?

6 A. Yes.

7 Q. The title of that is "Talc and Carcinoma of the  
8 Ovaries and Cervix." Do you see that?

9 A. Yes, I do.

10 THE COURT: We don't have to go through all  
11 these. You can just look at the list. We've already  
12 gotten some answers, and I think the question is  
13 whether they were cited or not.

14 Did you read them or consider them when you  
15 wrote your report, those that were available before  
16 you wrote your report?

17 THE WITNESS: For sure some of these. I can't  
18 be sure all of them I read before the report.

19 BY MR. TISI:

20 Q. No. 2, No. 4, No. 5, No. 6, and No. 7 all deal  
21 with inflammation and talc. Correct?

22 A. They probably all have some bearing on  
23 inflammation.

24 Q. You have a section in your report dealing with  
25 inflammation as a potential biologic mechanism for

1 inducing ovarian cancer. Correct?

2 A. There is a topic about that.

3 Q. Several pages, single-spaced pages, talking  
4 about the evidence. Correct?

5 A. Can you point me to it? I want to make sure  
6 we're looking at the same thing.

7 Q. If you go to page 40.

8 A. I'm with you.

9 Q. You go on for several pages on inflammation and  
10 the biologic plausibility of talc inducing  
11 inflammation?

12 A. If several is 2 1/2, I agree with you.

13 Q. None of these studies are discussed. Correct?

14 A. Not here.

15 Q. Now, you understand the purpose of this  
16 particular hearing is to focus on methodology and not  
17 conclusions. Correct?

18 A. That's what I've heard.

19 Q. We're not here to determine whether or not your  
20 conclusion is correct, or, for example,  
21 Dr. McTiernan's conclusion is correct. Correct?

22 Do you understand that?

23 A. I'm not sure that's entirely true one way or the  
24 other, but I believe you.

25 Q. Let me ask you this, Doctor: Would you agree

1 all studies, irrespective of design, have strengths  
2 and weaknesses?

3 A. Generally speaking, that is true.

4 Q. That would include even controlled clinical  
5 trials. True?

6 A. Absolutely.

7 Q. Would you agree scientists often do disagree  
8 about the relative strengths and weaknesses -- let's  
9 focus on epidemiology studies.

10 A. I didn't hear the whole question.

11 Q. Would you agree scientists and epidemiologists  
12 often disagree about the relative strengths and  
13 weaknesses about epidemiologic studies?

14 A. I'm sure that happens.

15 Q. Would you agree that while the Bradford Hill  
16 considerations are sometimes called criteria, they are  
17 not really criterion in the sense of clicking off  
18 boxes?

19 A. They are often called criteria, and I agree with  
20 you that it is not a checklist with boxes.

21 Q. If I could, I'm going to show you, rather than  
22 showing you an exhibit --

23 MR. TISI: And, your Honor, it is on page 133.

24 Q. You referred to Dr. Gordis as one of your  
25 teachers?

1 A. That's correct.

2 MR. TISI: Your Honor, he is one of the  
3 editors --

4 THE COURT: That's okay. I wasn't handed up  
5 plaintiffs' book.

6 (Pause.)

7 MS. BROWN: Where in the book, counsel?

8 MR. TISI: It's 133.

9 Q. He has a chapter on "From Association to  
10 Causation Deriving Inferences From Epidemiologic  
11 Studies." Do you see that?

12 A. I do.

13 Q. This is a chapter you are familiar with. Have  
14 you seen this book before?

15 A. So there are a couple of editions I have seen.  
16 I think the Fifth edition. And I have the current  
17 one, which is either 2018 or 2019. I don't know how  
18 many changes they make from edition to edition, but if  
19 this is an edition I have seen, then, yes.

20 Q. Would you go to page 260. I'm going to ask you  
21 if you agree with this, Doctor. It says:

22 "Although causal guidelines discussed in this  
23 chapter are often referred to as criteria, this term  
24 does not seem entirely appropriate. Although it may  
25 be a desirable goal to place causal inferences on a

1 firm quantitative and qualitative and structural  
2 foundation, at present we do not have all the  
3 information needed for doing so."

4 Do you agree with that?

5 A. I don't think with that second sentence. This  
6 is a conversation we frequently have, is whether to  
7 call them criteria. Bradford Hill called them  
8 considerations, whatever that means. Criteria is a  
9 pretty conventional term. I don't know what's  
10 inappropriate about it. It is certainly stuff that  
11 epidemiologists talk about all the time.

12 Q. He goes on to say:

13 "The preceding list should therefore be  
14 considered only guidelines that can be of most value  
15 when coupled with reasoned judgment about the entire  
16 body of available evidence in making decisions about  
17 causation."

18 Is that true?

19 A. I agree with it completely.

20 Q. Does reasoned judgment play a role in deciding  
21 whether or not cause and effect takes place?

22 A. Of course, because it is not a statistical test  
23 or something where there is an exact answer.

24 Q. So scientists can and often do disagree with the  
25 ultimate conclusion applying the very same

1 methodology. True?

2 A. I don't know how often. You asked me before  
3 about individual studies and about disagreeing about  
4 the relative importance. I can't speak for everybody,  
5 but I can speak for reasonable scientists that I know,  
6 and I think if it's a close call maybe people  
7 disagree. But I don't think it's just a general  
8 proposition it's all over the map.

9 Q. I'm going to ask you this, Doctor. You  
10 understand before your report was issued in February  
11 of this year, but after the plaintiffs' reports were  
12 due, Health Canada issued a report involving talc and  
13 among other things ovarian cancer?

14 A. I'm aware of that.

15 Q. The Judge has heard a lot about it, but I would  
16 like to spend a little bit of time with it. You read  
17 that document?

18 A. I have.

19 Q. It is dated December 2018, and it is Exhibit  
20 No. 56 in your binder, your Honor. This document is  
21 dated December 2018.

22 A. I don't think I have a 56. I'll follow along  
23 with you and maybe find a copy if I need to.

24 Q. This document -- let's talk about how this  
25 document came about, to the best you know, by reading

1 it.

2 First of all, when this document came out.  
3 You understand Health Canada, first of all, is the  
4 Canadian equivalent of the United States Food and Drug  
5 Administration. Correct?

6 A. I don't really know what their role is, and I  
7 don't know whether the equivalent of any particular  
8 agency. I know they are involved in health issues.  
9 But I don't know how they relate to the FDA.

10 Q. You understand, Doctor, before they issued this  
11 particular report, they went ahead and Health Canada  
12 asked for a study to be performed by an outside  
13 contractor which ultimately became what has been  
14 referred to as the Taher analysis.

15 Do you understand that?

16 A. Yes.

17 MR. TISI: The Taher analysis, for the record,  
18 is Exhibit No. 63.

19 Q. If you go to Exhibit No. 63, you go to page --  
20 it was funded by Health Canada. It's right in the  
21 back there. Do you see that?

22 A. I do.

23 Q. And following that, you understand that Health  
24 Canada actually drafted this report. Correct? "This  
25 report" being the screening assessment?

1 A. That's my understanding.

2 Q. Do you understand this was peer-reviewed?

3 A. I don't know what process it went through. And  
4 we're talking about Health Canada or Taher?

5 Q. Health Canada?

6 A. Because Taher has not been peer-reviewed.

7 Q. If you would go to Health Canada on page 1 of  
8 the document.

9 A. I don't have the document.

10 (Pause.)

11 Q. At the very bottom of page 1 it says:

12 "The human health portion of this assessment  
13 has undergone external peer review and/or  
14 consultation"? Did you note that when you reviewed  
15 this before.

16 A. I did read that. I just didn't recall it.

17 Q. The human health portion contains what we  
18 understand to be Health Canada's Bradford Hill  
19 analysis. Correct?

20 A. It includes that. That's right.

21 Q. If you go to the very beginning, you say in your  
22 expert report -- on page 49 you say:

23 "At the end of the day the Health Canada  
24 assessment failed to conclude that talc use causes  
25 ovarian cancer, and plaintiffs' experts misread the



1 report to the extent that they said that it did."

2 See that?

3 A. I do.

4 Q. You go on to say at the very beginning of your  
5 expert report, it says:

6 "The assessment by Health Canada and the  
7 related analysis by Muhammad Taher and others," you  
8 reviewed those documents and you're consistent with  
9 the opinions set forth above.

10 Do you see that?

11 A. Did you read something else?

12 Q. On page 47 of your report, you represent the  
13 assessment by Health Canada and the related analysis  
14 by Muhammad Taher is consistent with the opinions you  
15 set forth above. Do you see that?

16 A. (No response.)

17 Q. "And they do not support a conclusion that talc  
18 causes ovarian cancer."

19 A. That's correct.

20 Q. That's not true, is it?

21 A. It is true. All you have to do, if you read to  
22 the end of the Taher article, they arrive at the same  
23 place IARC did. They use the same language, and they  
24 even evoke IARC by saying the 2010 monograph -- they  
25 endorse the exact same conclusion IARC did. It is

1 absolutely not true they said there is cause.

2 Q. Would you turn to the Health Canada draft  
3 assessment, page Roman numeral III. This is a  
4 synopsis of the entire report. Correct?

5 A. Yes.

6 Q. We pulled out what it says about their analysis.  
7 It says:

8 "The meta-analyses of available human studies  
9 in the peer-reviewed literature indicate a consistent  
10 and statistically significant positive association  
11 between perineal exposure to talc and ovarian cancer.  
12 Further, available data are indicative of a causal  
13 effect."

14 Do you see that, Doctor?

15 A. I do.

16 Q. I assume you disagree with that because in your  
17 deposition you called that -- I think the words you  
18 said were it was ridiculous?

19 A. I don't know for a fact it was ridiculous. But  
20 the part of the Bradford Hill analysis was ridiculous.

21 This, by the way, is not the same as saying  
22 that they've arrived at a conclusion that talcum  
23 powder causes ovarian cancer. If they are assembling  
24 data, data could be indicative. Just like we looked  
25 at case-control studies, and a case-control study that

1 has a positive odds ratio is indicative of. But when  
2 you summarize all the evidence together, that's a  
3 different conclusion. So just to say there is  
4 available data is not the same as saying that talcum  
5 powder causes ovarian cancer.

6 Q. Let's look at what they did, Doctor.

7 Since this is about methodology, let's look at  
8 what the methodology they used and see whether or not  
9 it tracks the methodology that was used by you and by  
10 the plaintiffs' experts in this case.

11 If you go to page 15 in the section that was  
12 peer-reviewed, it talks about "perineal exposure to  
13 talc." Do you see that?

14 A. I'm with you.

15 Q. This is the section where they start talking  
16 about the analysis of the talc data. Correct?

17 A. That's right.

18 Q. And they acknowledge the IARC working group,  
19 which we will talk about in a moment, in the first  
20 paragraph. Right?

21 A. Acknowledge and recapitulate their conclusion.

22 Q. As background material. Correct?

23 A. Correct.

24 Q. Then they start to review the animal studies.  
25 Do you see that?

1 A. I do.

2 Q. And they then, the next section, they start  
3 talking about the human studies. This is what  
4 epidemiologists do. Correct?

5 A. Human studies?

6 Q. They looked at the animal studies and they  
7 looked at the human studies?

8 A. Epidemiologists look at the human studies, for  
9 sure, if we are talking about the relevant ones. I  
10 don't know that epidemiologists do a thorough review  
11 of animal studies and may look for a summary. But an  
12 epidemiologist will consider animal studies.

13 Q. Because that bears on the issue of biologic  
14 plausibility. Correct?

15 A. It does.

16 Q. So in this document Health Canada, after having  
17 had an analysis by the outside Taher group, they then  
18 write their own report, and in their own report they  
19 summarize the human data and the animal data.  
20 Correct?

21 A. That's correct.

22 Q. You will see table 6-1, which is a chart of many  
23 of the different epidemiology studies that you have  
24 talked about and Dr. McTiernan talked about. Correct?

25 A. Correct.

1 Q. Among the other things they list are the sample  
2 size, et cetera. Correct?

3 A. That's correct.

4 Q. If you go to page 18, they talk about "mode of  
5 action." See that?

6 A. I do.

7 Q. I want to pause here a minute and talk about  
8 some of the things Health Canada is looking at again  
9 only six months ago. Correct?

10 A. Correct.

11 Q. This is contemporaneous with what we are doing  
12 here today, correct, looking at the data?

13 A. I guess, yes.

14 Q. They say:

15 "With respect to talc specifically, local  
16 chronic irritation leading to an inflammatory response  
17 is one possible mechanism of tumor progression that is  
18 frequently hypothesized. It is known that persistent  
19 indications of inflammation, including C-reactive  
20 protein, tumour necrosis factor, and other  
21 inflammatory markers, are detected in the blood of  
22 women prior to a diagnosis of ovarian tumors."

23 Do you see that?

24 A. I do.

25 Q. It goes on at the bottom, the last sentence, it

1 says:

2 "There is support for an association of  
3 inflammation and increased risk of ovarian cancer,"  
4 citing the National Academy of Sciences."

5 Do you see that?

6 A. I do.

7 Q. I just want to confirm with you this is what  
8 people outside the courtroom -- you understand that  
9 Health Canada doesn't have anything to do with this  
10 litigation whatsoever. Correct?

11 A. I think they do now. Dr. McTiernan said they  
12 invited her to participate in the process so they are  
13 probably somehow linked. Otherwise, I don't know of  
14 any links.

15 Q. At the time of this report you have no evidence  
16 that they were involved in this litigation.

17 A. No, of course not.

18 Q. They are looking at the data; and if we are  
19 trying to assess whether or not the experts in this  
20 case are acting reasonably in their interpretation of  
21 the data and studies, one of the places we might look  
22 is to look at, as you pointed out, what people outside  
23 at the courtroom are doing. Correct?

24 A. It includes that.

25 Q. One of the things they are looking at here is,

1 this isn't some harebrained idea that there is  
2 inflammation, is a biologically plausible mechanism;  
3 this is something that the scientists at Health Canada  
4 looked at and assessed and put into their report.

5 I'm not asking whether they are correct or not  
6 correct. I'm asking you whether or not this is the  
7 kind of information that experts did outside the  
8 courtroom.

9 A. This was done outside the courtroom. Can you  
10 repeat the first part of the question? I lost you by  
11 the time we got there.

12 Q. Doctor, if you would look, this whole discussion  
13 of inflammation is something that the scientists in  
14 Health Canada were doing independent of what  
15 plaintiffs' experts and you were doing when you were  
16 preparing your expert report. Correct?

17 A. Correct.

18 Q. If we are trying to check whether or not the  
19 methodology that was being used by the experts in  
20 trying to decide the question whether or not talcum  
21 powder products cause ovarian cancer inflammation and  
22 this discussion of the studies here are some  
23 corroboration of that. True?

24 A. Oh, my gosh. Some corroboration is very  
25 different. This says that local chronic irritation is

1 a possible mechanism that is frequently hypothesized.  
2 Hypothesis is something you serve up in order to test  
3 whether it is true or not. So to me to lead in with  
4 that really is consistent with all of the uncertainty  
5 I have seen expressed by other authors. That's not  
6 the same as it's been demonstrated.

7 Q. Don't they go on and cite studies that support  
8 that hypothesis?

9 A. Sort of. We have Trabert by 2014.

10 Q. I'm just asking whether they cited articles that  
11 support the hypothesis.

12 A. Yes, indeed.

13 Q. On the next page they talk about migration.  
14 They call it translocation. They talk about different  
15 studies that deal with that issue?

16 A. Correct.

17 Q. The next paragraph after that they talk about  
18 whether or not talc gets to the ovaries via inhalation  
19 in the lymph nodes. Correct?

20 A. Are you saying --

21 Q. It says."

22 "Another possible mode of action that is  
23 hypothesized in the scientific literature is  
24 immune-mediated."

25 Do you see that?



1 A. I thought you asked if they said it was by  
2 inhalation.

3 Q. I withdraw that.

4 The next section here talks about a different  
5 mode of action other than migration. Correct?

6 A. That is correct.

7 Q. And they provide the support for that. Correct?

8 A. Correct.

9 Q. The next one is they talk about the  
10 meta-analysis. Correct?

11 A. Correct.

12 Q. And in there they talk about the fact that they  
13 had gone ahead and contracted a new meta-analysis by  
14 Taher. Correct?

15 A. They do.

16 Q. And then they go through and they discuss each  
17 of the different Bradford Hill criteria. Correct?

18 A. They do.

19 Q. Let's take, for example, the strength of  
20 association. There is a discussion of that. Correct?

21 A. A discussion --

22 Q. Of the strength of association. Correct?

23 A. That's not a conclusion, though.

24 Q. I said they discuss it.

25 A. I understand. It is not the same as doing a

1     Bradford Hill analysis to discuss it. You actually  
2     have to do something with it.

3     Q.     They are considering each and every one of the  
4     Bradford Hill criteria in this document. Correct?

5     A.     They do.

6     Q.     The first one they consider is "strength," and  
7     they discuss the meta-analyses and what is seen in the  
8     meta-analyses. Correct?

9     A.     They include that.

10    Q.     One of the things that they say, and I want to  
11    spend a moment with this paragraph on page 20, it  
12    says:

13             "The individual cohort studies did not show a  
14    statistically significant association between perineal  
15    talc use and ovarian cancer."

16             Correct?

17    A.     That's correct.

18    Q.     They go on to give reasons why that might have  
19    under-estimated the risk. Correct?

20    A.     They give some reasons why that could be.

21    Q.     "However, there was a positive association."  
22    See that?

23    A.     In the case-control studies.

24    Q.     No --

25    A.     I'm sorry. With the serous ovarian.

1 Q. Correct.

2 (Reading.)

3 "However, there was a positive association  
4 with statistical significance, specific to invasive  
5 serous-type ovarian cancer in the cohort studies."

6 Do you see that?

7 A. I do.

8 Q. It says:

9 "Given the long latency for ovarian cancer,  
10 the follow-up periods may not have been sufficient to  
11 capture all the cases for the individual cohort  
12 studies."

13 Do you see that?

14 A. I do.

15 Q. They are identifying the very same kind of  
16 issues that you heard Dr. McTiernan talk about  
17 yesterday. Correct?

18 A. Some of these, yes.

19 Q. The next thing -- and, of course, as we talked  
20 about before, Dr. McTiernan had no involvement in this  
21 process of developing this report, to your knowledge?

22 A. As far as I know, she did not.

23 Q. The next thing it says:

24 "Given the rarity of ovarian cancer, many of  
25 the available human studies may not be sufficiently

1 powered to detect a low odds ratio."

2 Do you see that?

3 A. I do.

4 Q. It goes on to say:

5 "With larger sample sizes, more individual  
6 studies may have demonstrated stronger associations."

7 These are the very kinds of things that  
8 Dr. McTiernan and plaintiffs' experts identified  
9 totally independent of this analysis. Correct?

10 A. These are the same things most of the folks  
11 involved here have identified. They didn't go out and  
12 discover something new. They've assembled some of the  
13 same stuff that's out there.

14 Q. If you go to the Taher report, they also talked  
15 about the issue of nondifferential misclassification  
16 because the people in the cohort studies, the women in  
17 the cohort studies were only interviewed once during  
18 the course of the study about their talc use. Do you  
19 remember that?

20 A. Yes. They hypothesized that was a possibility.  
21 They didn't demonstrate that was a truth or a fact.

22 Q. Doctor, you hypothesized recall bias was an  
23 issue with these studies, that confounding was an  
24 issue with these studies?

25 A. What's kind of cool, though, is that I actually

1 showed an exact example from these particular  
2 epidemiologic studies which demonstrated it exactly.  
3 So it's not just a hypothesis. It's actually a fact  
4 based on at least the one study.

5 Q. What I'm trying to ask you, Doctor, is outside  
6 the courtroom the scientists who were looking at the  
7 same question you and Dr. McTiernan were looking at  
8 were considering the very same kind of issues that you  
9 and Dr. McTiernan talked about over the past two days.  
10 Correct?

11 A. Generally speaking, I'd say there is some  
12 overlap with at least the content of what these are.

13 Q. The next issue is on "consistency." You  
14 testified there is no consistency. Correct?

15 A. I did not. I said when you look at the  
16 information in total, that it doesn't satisfy the  
17 consistency criterion because what I said was  
18 including that you are not just looking for a couple  
19 of examples where a couple of studies may be  
20 consistent with each other, but does the total body of  
21 evidence show consistency.

22 Q. Well, Health Canada addressed that issue, did  
23 they not, outside of the courtroom?

24 A. They did.

25 Q. They said:

1 "Several meta-analyses conducted over the past  
2 15 years calculated similar odds ratios and resulted  
3 in similar conclusions."

4 Did I read correctly?

5 A. You did.

6 Q. It says:

7 "There is a small yet consistent and  
8 statistically significant increased risk for ovarian  
9 cancer with perineal talc use," and cites the very  
10 same studies that you and Dr. McTiernan have talked  
11 about over the past two days. Correct?

12 A. Yes.

13 Q. They go on to say:

14 "The epidemiological studies examined in these  
15 meta-analyses were conducted over different periods of  
16 time across more than four decades among different  
17 ethnicities and spanned many geographical areas  
18 worldwide."

19 Do you see that?

20 A. I see it. They don't say whether there is  
21 consistency or not. You are exactly right. They are  
22 describing the same sorts of things Dr. McTiernan and  
23 I considered. But I also evaluated. I don't see an  
24 evaluation here whether they are consistent.

25 Q. Doctor, in fairness, let me ask you this: What

1 is the importance of replication?

2 A. In what context?

3 Q. For epidemiology.

4 A. It is so abstract, I'm not sure what you mean.

5 Q. Does Dr. Gordis deal with that issue?

6 A. I'm sure he probably does.

7 Q. One of the important things about studies, not  
8 when you are looking at an individual studies, but  
9 when you are looking at multiple studies, is to see  
10 whether or not those studies were conducted in  
11 different populations with different researchers in  
12 different areas under different conditions using  
13 different study designs.

14 A. Yes.

15 Q. By doing that, you reduce the issues of  
16 confounding, bias, chance. Correct?

17 A. No, not necessarily. The biases that we're  
18 talking about in this case, such as information bias,  
19 would function the same way. That's why when you find  
20 a very small risk, it is not surprising to find that  
21 small risk in different places. So the reason recall  
22 bias functions in sick people differently than healthy  
23 people, regardless of where they are, and when people  
24 are shy or reluctant to talk about something  
25 sensitive, that functions across countries as well.

1 It doesn't necessarily take care of that problem.

2 And the confounders you still have to assess  
3 them and acknowledge them. Just doing studies in  
4 multiple countries doesn't take care of confounders if  
5 you don't assess the confounders.

6 Q. Doctor, one of the issues you raised is  
7 douching. Correct? Correct?

8 A. Correct.

9 Q. Douching was based upon what study?

10 A. The Gonzalez study.

11 Q. And the Gonzalez was a United States study?

12 A. It is.

13 Q. There were multiple studies conducted around the  
14 world, correct, case-control studies?

15 A. There are a few that were world-wide and most  
16 U.S..

17 Q. There were three studies in Australia, one study  
18 in China, one study in Greece, a study in Israel,  
19 several studies in Canada. Correct?

20 A. Correct.

21 Q. In order to assess that question -- do you know  
22 whether or not douching is even something that is a --  
23 in order to be a confounder, douching would have to be  
24 associated with the use of talc?

25 A. If it is going to confound the relationship



1 between talc and ovarian cancer.

2 Q. Because confounding doesn't mean confusion.

3 There is a very specific formula or criteria to meet  
4 the criteria to be a confounder. Correct?

5 A. It is definitely not confusion.

6 Q. It has to be associated with the item under  
7 study. Correct?

8 A. In order to confound the relationship between  
9 the exposure and the outcome.

10 Q. And so when you went and were looking at the  
11 issue of douching, did you go and make any effort to  
12 see whether or not in the other countries, in  
13 Australia where they found statistically significant  
14 increased risk in the case-control studies; in China,  
15 where there was an increased risk, did you go and see  
16 whether or not women douched in connection with the  
17 use of talcum powder products?

18 A. There are a couple of questions. I did look at  
19 every single study I had available to me to see  
20 whether or not douching was accounted for. There was  
21 one case-control study that did account for it, and I  
22 think there may be a second I found subsequent to  
23 that. That was all that I found.

24 Separately if there is a relationship between  
25 douching and talcum powder use -- they for sure looked

1 at that in the Gonzalez study. I don't remember  
2 whether any of the other studies looked at the  
3 concordance of those two habits.

4 Q. Did you go and see whether or not there was any  
5 data in any of the other countries in which  
6 douching -- because to be a confounder, it would have  
7 to be related to the use of talcum powder and see  
8 whether or not there's any use data that would confirm  
9 that as a confounder in those countries?

10 A. I think I just answered you. I said I went and  
11 looked at every single study for what they assessed  
12 about douching.

13 I know for sure the Gonzalez study looked at  
14 the correspondence of the two habits. Together they  
15 had an odds ratio of 2.1 for the relationship between  
16 the two of them, and I don't recall whether there was  
17 -- there is only one study or two studies at most that  
18 even accounted for douching.

19 Q. That wasn't my question. There are three  
20 Australian studies. Correct?

21 A. I don't remember the count. I believe you.

22 Q. There were three Australian studies, Purdie,  
23 Green, and Merritt, all statistically significant in  
24 Australia. Correct?

25 A. I'm confused by your title.

1 THE COURT: This is listed as recall bias and  
2 not douching. Based on that title, how does he know  
3 they are douching?

4 Q. The studies did not adjust for douching. These  
5 three studies did not adjust for douching.

6 My question is: Do you know whether or not  
7 women in Australia even douche?

8 A. I have no idea.

9 Q. Do you know whether or not that it is associated  
10 with the use of talcum powder products in Australia?

11 A. No idea.

12 THE COURT: You are asking about the studies.  
13 I would like to move on. You are asking about has he  
14 considered studies in this connection. I thought you  
15 were pointing these out as ones that considered it.  
16 We started with Gonzalez. He said he clearly did. I  
17 don't know where we are going with some hypotheticals,  
18 whether they do. You don't know either. Maybe you  
19 do.

20 Q. Going back to the Health Canada assessment, if  
21 you look at the specificity section, they talk about  
22 that. Correct?

23 A. They do.

24 Q. They identify specificity, that the cancers are  
25 specific to the ovaries as opposed to any other of the

1 female anatomy. Correct?

2 A. They've gotten that so incorrect. That's not  
3 what specificity means in the Hill criteria.

4 Q. You may disagree with their assessment but they  
5 assessed it. Correct?

6 A. Well, in a couple of cases I don't see that they  
7 assessed to reach a conclusion. They just put down  
8 some things they might have considered. In some of  
9 these cases they are saying stuff that isn't true.  
10 For temporality, that you brought up, you said in all  
11 case-control studies, reporting positive outcomes, the  
12 participants recalled the exposure to talc preceded  
13 the reported outcome. Well, of course, that's true.  
14 That's what happens in cross-sections, that you can  
15 ask the people about the past. That's not the same as  
16 demonstrating temporality. So they've actually  
17 reported something here that doesn't show temporality.

18 It's just like the specificity thing, where  
19 they say perineal talc exposure is specifically  
20 associated with cancer of the ovary. There has to be  
21 a one-to-one association between the exposure and the  
22 outcome, generally speaking, which is super rare.  
23 This is just a sentence where they have the word  
24 "specifically" in it.

25 Q. Do you disagree with them?

1 A. I disagree that that particular sentence is  
2 supportive of the notion of specificity, even though  
3 they've used the English word "specifically" in it.

4 Q. They also addressed "biological gradient," which  
5 is dose-response?

6 A. Right. They say there is a lack of available  
7 exposure effect relationship.

8 Q. They also say that seven studies provided some  
9 evidence of increased risk of ovarian cancer with  
10 increasing perineal applications of talc, although the  
11 evidence wasn't clear. Correct?

12 A. Yes.

13 Q. Does the Bradford Hill criteria require that  
14 there be consistent statistically significant  
15 increased risk for dose-response in order for this  
16 criteria to be met?

17 A. None of the Bradford Hill criteria are required  
18 including that one.

19 Q. "Biological plausibility," do they deal with  
20 that issue, the next page? Do they talk about the  
21 issue of biological plausibility?

22 A. Yes.

23 Q. Do they say, "the presence of talc in the  
24 ovaries has been documented"?

25 A. They do.

1 Q. "This evidence of retrograde transport supports  
2 the biologic plausibility of the association between  
3 perineal talc application and ovarian exposure."

4 Correct?

5 A. They do.

6 Q. And although they also say that the specific  
7 cascade has not been established, you would agree that  
8 they do discuss the biologic plausibility of migration  
9 as being a mechanism by which talc gets to the  
10 ovaries?

11 A. They do discuss it.

12 Q. They talk about "coherence" as well. Correct?

13 A. Yes.

14 Q. And at the conclusion of all of this, Doctor,  
15 they then make another statement that we talked about  
16 before from the synopsis. Correct? They say:

17 "The most recent meta-analysis detailed above,  
18 Taher 2018, and consistent with the Hill criteria,  
19 suggests a small but consistent statistically  
20 significant positive association between ovarian  
21 cancer and perineal exposure to talc. Further,  
22 available data are indicative of a causal effect."

23 Do they say that?

24 A. They do.

25 Q. They go on to say later on -- if you go to page

1 27, they repeat this statement, if you go to the  
2 middle of the page, it says:

3 "Data from published meta-analyses of  
4 epidemiological studies indicate a consistent and  
5 statistically significant positive association between  
6 perineal exposure to talc and ovarian cancer."

7 Do you see that?

8 A. I do.

9 Q. They quote another article which you are  
10 familiar with; it says:

11 "It is unlikely that the association between  
12 talc and ovarian cancer is due to confounding, and so  
13 it is fair to say that there is a statistically robust  
14 relationship between talc use and ovarian cancer, it  
15 is likely to be causal."

16 MS. BROWN: Counsel, I think you read that  
17 incorrectly.

18 Q. It says:

19 "It is unlikely that the association between  
20 talc and ovarian cancer is due to confounding and so  
21 it is fair to say that if there is a statistically  
22 robust relationship between talc use and ovarian  
23 cancer, it is likely to be causal."

24 Do you see that?

25 A. I do.

1 Q. And so outside the courtroom, separate and apart  
2 from litigation, Health Canada did three things:

3 First, it commissioned the Taher study?

4 A. Correct.

5 Q. Second, it wrote a report?

6 A. A draft report.

7 Q. Third, it had that draft report peer-reviewed?

8 A. Somehow.

9 Q. And, fourth, it published it. Correct?

10 A. I don't know what "published" means. It's  
11 available.

12 Q. Made it available?

13 A. Yes.

14 Q. If you go back to page 27 of the assessment,  
15 after the sentence I read below, it says:

16 "Similarly, Penninkilampi and Eslick noted the  
17 confirmation of an association in cohort studies  
18 between perineal talc use and serious invasive ovarian  
19 cancer is suggestive of a causal association."

20 See that?

21 A. I would call it serous probably rather than  
22 serious just so that it's correct.

23 Q. That is the sentence we read before from the  
24 Penninkilampi study?

25 A. Yes, it's the same one.



1 Q. "Taher and colleagues noted that consistent with  
2 previous evaluations by the International Agency for  
3 Research on Cancer 2010, and more recent and  
4 subsequent evaluations by individual investigators,  
5 the present comprehensive evaluation of all currently  
6 available relevant data indicates that perineal  
7 exposure to talc is a possible cause of ovarian cancer  
8 in humans."

9 Correct?

10 A. Did they say that? Yes --

11 MS. BROWN: Can he be permitted to finish his  
12 answer?

13 MR. TISI: I just asked whether it says that.

14 THE COURT: Well, these are quoting. So we  
15 have to be clear. It is the article, whatever this  
16 is, the draft screening report, quoting these various  
17 sources you've already discussed. It is not the  
18 language of the Canadian people. It is their quotes  
19 from these articles.

20 MR. TISI: Correct.

21 THE COURT: Now, we can continue.

22 MS. BROWN: Thank you.

23 THE COURT: Can I just ask, and maybe there is  
24 not an answer any of you can give me, but is there  
25 anywhere that reflects what the peer review was of

1 this Canadian report?

2 MR. TISI: I just have what you have, your  
3 Honor.

4 THE COURT: All right.

5 BY MR. TISI:

6 Q. The next thing I want to do is I want to go to  
7 the Taher paper. Do you have that in front of you?

8 A. Not anymore. Is it in this binder?

9 MS. PARFITT: It is number 63.

10 THE WITNESS: Thank you.

11 Q. On page 43 -- and this is outside of litigation.  
12 You have no reason to believe that any of the Taher  
13 authors have anything to do with this litigation.  
14 Correct?

15 MS. BROWN: Objection, your Honor. It calls  
16 for him to speculate. How would he know either way?  
17 It may very well have been funded by plaintiffs'  
18 lawyers.

19 MR. TISI: It is not funded by plaintiffs'  
20 lawyers.

21 THE COURT: I understand your representation.  
22 The question is: Do you know if the Taher report was  
23 funded by any plaintiffs' lawyers?

24 THE WITNESS: I'm not aware of that.

25 BY MR. TISI:

1 Q. On page 43, the authors talk about the cohort  
2 studies. Correct?

3 A. They do.

4 Q. On page 43 they discuss three of the issues you  
5 talked about before with respect to the talc studies,  
6 do they not?

7 A. Are there three? I don't know.

8 Q. The first one they talk about is latency. Do  
9 you see that?

10 A. Yes.

11 Q. (Reading.)

12 "Although cohort study designs are efficient  
13 for examining diseases with a long latency period, it  
14 is essential that the period between talc exposure and  
15 the cancer diagnosis be sufficiently long."

16 See that?

17 A. I do.

18 Q. And they identify the cohort studies may not be  
19 long enough to truly identify ovarian cancer related  
20 to talc, do they not?

21 A. So --

22 Q. I'm asking whether they identify that as a  
23 potential weakness of the cohort studies outside of  
24 litigation.

25 A. They are talking about latency here, and they

1 are talking about latency. I agree with you.

2 Q. One of the things counsel asked you before is  
3 whether or not in assessing epidemiology studies, in  
4 your experience, whether or not there is anything  
5 different between cancer and the study of any other  
6 kind of disease. Do you remember that?

7 A. Who asked that?

8 Q. Counsel for Johnson & Johnson.

9 A. Today?

10 Q. Yes.

11 A. Really?

12 Q. Asked you with your qualifications.

13 Do you remember earlier on you were asked a  
14 question about your qualifications, whether or not  
15 your qualifications -- somebody with training in  
16 epidemiology, who is primarily a pulmonary physician,  
17 whether or not that allows you to analyze studies on  
18 cancer? Do you remember that question?

19 A. Not exactly. But I can answer it again if  
20 that's is helpful.

21 Q. I'm asking you this: Do you know what the  
22 latency period is for ovarian cancer?

23 A. From what?

24 Q. I'm asking you.

25 A. I know, but it's an incomplete question. If you

1 ask, What's the latency for lung cancer?, you have to  
2 know what the exposure is you are talking about. If  
3 you ask, What's the latency for mesothelioma?, you  
4 have to know what it is you are talking about because  
5 the latency differs depending upon which exposure.

6 Q. Have you done research into that?

7 A. Research in the sense that I've looked to find  
8 whether or not there is a known latency period between  
9 talcum powder and ovarian cancer, and there is not.

10 Q. And whether or not these studies are long enough  
11 to actually capture that risk?

12 A. They do seem to be long enough in general.

13 You are highlighting the Gonzalez study right  
14 there. All of these studies have older women, and  
15 they are describing something that's a habit. When  
16 they ask them about talcum powder, it wouldn't have  
17 been just on the day they asked them the question.  
18 They are documenting a habit as opposed to just a  
19 one-time event.

20 The Gonzalez study also asked about  
21 pre-pubertal girls also, and so they have evidence  
22 going back that many decades. These are mature women  
23 that were enrolled in the study. So they actually  
24 have that kind of time.

25 What I would say too because you showed me

1 Narod before, and Narod said we would need 200,000  
2 women followed for 10 years, and with all three of  
3 these studies, you have 200,000 women who were already  
4 followed for 12 years, and of the other ones was an  
5 average of eight years. So you are getting awfully  
6 close to the right amount of time, according to Narod.

7 One of the studies asked about talcum powder  
8 use in the 20 years prior to the study. I don't think  
9 you can sort of say in general there is not enough  
10 time that's gone by. And that's even assuming you  
11 knew, which I don't know how anybody could know, what  
12 the latency period is between talcum powder and  
13 ovarian cancer.

14 Q. One of the advantages of a case-control study is  
15 you can interview people after the fact and find out  
16 when their exposure began?

17 A. You can hope to. But that's the disadvantages,  
18 that's it's a hope to, because --

19 Q. Doctor, one of the advantages of a case-control  
20 study is you can interview women about their use  
21 looking backwards. Correct?

22 A. You can interview them, yes.

23 Q. And you can try and get information as best you  
24 can about when they started to be exposed to the issue  
25 at interest?

1 A. You can try to.

2 Q. You can't really do that in a cohort study, can  
3 you?

4 A. You do that because you are assessing the people  
5 at some certain baseline, and you can also ask  
6 questions of the women at baseline.

7 The same question is available to a person who  
8 is enrolling in a cohort study as in a case-control  
9 study.

10 Just to be clear. You can ask a woman who is  
11 enrolling in either type of study, What were your  
12 habits last week? 10 years ago? 20 years ago? That  
13 question can be asked in any study design.

14 Q. So getting back to my original question, the  
15 issue of latency is an issue that was raised outside  
16 of litigation in this study. Correct? The issue of  
17 whether or not the cohort studies were long enough was  
18 addressed outside of the courtroom.

19 A. That is correct.

20 Q. That is an issue both you and Dr. McTiernan  
21 addressed in your reports?

22 A. That is correct.

23 Q. You have a disagreement?

24 A. I don't remember what she says about latency.  
25 If it's other than what I said, then I disagree with

1 her.

2 Q. The next one is under power. Do you see the  
3 next sentence? This is the issue you were just  
4 talking about as to whether or not the cohort studies  
5 were large enough. Correct?

6 A. Large enough to what?

7 Q. Large enough to detect an association.

8 A. That's where there is a mistake. Any size study  
9 can detect an association. But if we are talking  
10 about power, we are talking about something different.

11 Q. But the issue of whether or not these studies  
12 were adequately powered to detect an association is an  
13 issue that was raised outside of litigation. Correct?

14 A. Absolutely.

15 Q. And it's an issue you have addressed in your  
16 report. Correct?

17 A. Correct.

18 Q. And it's an issue Dr. McTiernan and plaintiffs'  
19 other experts addressed in their reports. Correct?

20 A. That's correct.

21 Q. And it's an area upon which you disagree.  
22 Correct?

23 A. Yes.

24 Q. Next page, page 44, they talk about the issue of  
25 nondifferential misclassification. Correct?



1 A. They do.

2 Q. Remind us again what nondifferential  
3 classification is?

4 A. It's a broad category of whether people are  
5 assigned to the wrong exposure but without there being  
6 information that drives that; meaning that it's sort  
7 of like a random or a haphazard kind of relationship  
8 as opposed to it being determined by something in  
9 particular.

10 Q. It's an information bias. Correct?

11 A. It functions as an information bias.

12 Q. And if you have nondifferential  
13 misclassification unlike recall bias which can be an  
14 exaggerated effect, nondifferential misclassification  
15 is a bias that can attenuate an effect?

16 A. Absolutely.

17 Q. It's something you noted in your literature as  
18 well. Correct?

19 A. What's my literature?

20 Q. In your cohort studies there is always an issue  
21 you have to consider of nondifferential  
22 misclassification?

23 A. Sure.

24 Q. And that's one of the issues that's being  
25 addressed here, whether or not assessing women at one

1 time in the cohort studies about their exposure to  
2 either talc or powders is sufficient to, has a  
3 potential of introducing nondifferential  
4 misclassification?

5 A. Correct.

6 Q. That's an issue that was identified outside the  
7 courtroom. Correct?

8 A. Correct.

9 Q. It was addressed by you in your report.  
10 Correct?

11 A. Correct.

12 Q. It was addressed by Dr. McTiernan and Dr.  
13 Siemiatycki. It was addressed by Dr. Moorman.  
14 Correct?

15 A. Correct.

16 Q. It was addressed Dr. Singh. Correct?

17 A. I'm sure, but I don't remember.

18 Q. It was addressed by Dr. Smith-Bindman?

19 A. Yes.

20 Q. And it's an area where you all addressed it and  
21 you have a disagreement. Correct?

22 A. What's the disagreement?

23 Q. About the effect of nondifferential  
24 misclassification in the cohort studies?

25 A. What the effect of it is? I don't think I

1 disagree with how it works.

2 Q. I'm asking whether it was assessed by all the  
3 experts in this case?

4 A. Yes, it was.

5 Q. This wasn't a situation where people were  
6 ignoring the potential of this bias?

7 A. Nobody was ignoring bias or confounding or  
8 chance.

9 Q. And so what I'm trying to ask you, Doctor, is  
10 both the Health Canada assessment and the Taher  
11 assessment were doing in parallel what you and I are  
12 doing here today; they were trying to make sense of  
13 the data and trying to see whether or not using the  
14 Bradford Hill criteria there was a cause and effect.  
15 Correct?

16 A. Taher was a meta-analysis. They did comment on  
17 cause and effect, and I think the draft Health Canada  
18 document is also trying to consider whether there is  
19 cause and effect.

20 Q. So my question to you is, Doctor, totally  
21 separate from being involved in this litigation in  
22 this courtroom, in this courthouse in Trenton, New  
23 Jersey, people were doing the very same kind of  
24 analysis that you and Dr. McTiernan were talking about  
25 the past two days?

1 A. I don't think it's the exact same one.

2 Q. I didn't say the exact same.

3 A. I thought I heard you say exact same.

4 THE COURT: It was very same.

5 Q. They were doing a Bradford Hill analysis of the  
6 available data looking at the very same studies that  
7 we have all been talking about. Correct?

8 A. No. They evoked the term Bradford Hill  
9 analysis, and they didn't uniformly do a Bradford Hill  
10 analysis. That's when we looked at some of those  
11 criteria you asked me to looked at, did they discuss  
12 it? Yes, they discussed it, but that is not the same  
13 as analyzing it.

14 Q. Doctor, outside the courtroom, totally separate  
15 from what we are doing here, they analyzed, assessed  
16 the very data that we have been talking about --  
17 Penninkilampi, Eslick, case-controls, the cohorts --  
18 they are all here. Correct?

19 A. I think you just twisted back what I just said  
20 because I don't think in some cases they did assess.  
21 They acknowledged certain things, but they didn't  
22 always reach an assessment.

23 Q. How do you know that?

24 A. I read it. That's what I'm saying. The point I  
25 where I was asking -- am I allowed to comment? And

1 you said, no. You're just reading it. So we're just  
2 reading stuff in. One of my comments would have been  
3 is they just listed some things there, but they  
4 haven't reached a conclusion. Under strength of  
5 association they don't declare whether it's weak or  
6 strong as an example. So --

7 Q. Can you tell us but --

8 MS. BROWN: Can he be allowed to finish his  
9 answer before counsel asks another question?

10 THE COURT: Fine.

11 A. It's not enough to just say Bradford Hill, those  
12 headings, and then fill in some stuff underneath. You  
13 actually have to analyze it. And I'm saying based on  
14 what I read, they didn't uniformly do that.

15 Q. Let's move on.

16 THE COURT: Perhaps now is a good time to  
17 break for lunch, 12:30.

18 MR. TISI: Yes.

19 THE COURT: Basically, you used an hour and  
20 15 minutes. So you still have the bulk of your time  
21 left.

22 THE DEPUTY CLERK: All rise.

23 (Luncheon recess.)

24

25

**A F T E R N O O N       S E S S I O N**

(In open court.)

THE DEPUTY CLERK: All rise.

THE COURT: Thank you.

**GREGORY B. DIETTE**, resumed.

CROSS-EXAMINATION

BY MR. TISI:

Q. I want to back up a little bit. Let's see if we can get some things out of the way.

First of all, I want to ask you a little bit about your qualifications and then I'm going to talk about your methodology. So let me ask you a couple of questions right off of the bat.

You are not an oncologist. Correct?

A. Correct.

Q. You are Board Certified in pulmonology?

A. Pulmonology and internal medicine.

Q. There are people who actually do -- people who are oncologists and people who do cancer research as their primary focus of what they do. Correct?

A. That's correct.

Q. You are not one of those people?

1 A. I am not an oncologist, and that's my not my  
2 primary focus.

3 Q. Your research activities have not been focused  
4 on researching causes of cancer?

5 A. Not focused for sure. I've had some studies  
6 that pertained to cancer, but it has not been a focus.

7 Q. Your focus is pulmonary diseases, things like  
8 asthma, those kinds of things?

9 A. More environmentally caused diseases in general,  
10 including asthma, COPD, and other lung diseases.

11 Q. And there are people actually at Johns Hopkins  
12 who actually specialize in cancer epidemiology. True?

13 A. There have been. I assume there are. I don't  
14 know who they are at the moment.

15 Q. But people wouldn't, when they come to Johns  
16 Hopkins, say: I need a cancer epidemiologist; they  
17 typically wouldn't say I need to speak to you. Is  
18 that fair?

19 A. If somebody needed an epidemiologist, they might  
20 come to me. I honestly don't know what happens if  
21 somebody says: I want a cancer epidemiologist. I  
22 guess that's what I could say.

23 Q. Now, counsel provided some slides here about  
24 your background and research. Is any of that related  
25 to cancer or ovarian cancer?

1       A.       So the clinical work -- I'll start there.  
2       That's the part that slipped off the page there. So  
3       my clinical work includes training in cancer care as  
4       an internist; and one of my responsibilities in the  
5       hospital is to work in our oncology center. There's  
6       only people with cancer there. So cancer care is  
7       throughout the whole enterprise in a way. So I'll see  
8       people with cancer on the pulmonary service, on the  
9       internal medicine service. There are people with  
10      cancer in my clinic.

11             The other issues are in terms of my degree,  
12      part of that included studying cancer epidemiology as  
13      part of the clinical epidemiology degree that led me  
14      being a professor eventually of epidemiology, and the  
15      teaching I do has included teaching of oncologists and  
16      other folks who do that sort of research.

17      Q.       When Hopkins University puts information out  
18      about you, it does not indicate that your research  
19      interest primarily is cancer. True?

20      A.       You know, I think either your colleague maybe  
21      showed me something from our website. I don't know  
22      for the most part what my university puts out about  
23      me. There are a couple of websites out there that it  
24      seems as if only lawyers seem to care about. I don't  
25      know what else gets out there.



1 Q. This indicates your background as a professor of  
2 medicine -- I'm sorry -- and expertise and research  
3 interests?

4 Johns Hopkins University has Greg Diette, and  
5 it has your expertise as asthma, chronic obstructive  
6 pulmonary diseases, critical care medicine, pulmonary  
7 medicine, and it actually indicates your research  
8 interests are environmental impacts on lung disease.  
9 Is that correct?

10 A. That's what it says, yes.

11 Q. And epidemiology of airway disease?

12 A. Correct.

13 Q. And chronic obstructive pulmonary disease and  
14 asthma. Correct?

15 A. Correct.

16 Q. Your CV is in the record. That is really a good  
17 summary of your primary focus of your professional  
18 career?

19 A. I wouldn't limit it to that. I don't know what  
20 website that is and why it was so succinct, but those  
21 things are all true about me.

22 THE COURT: At the top corner it said "Find an  
23 Expert?"

24 THE WITNESS: I didn't populate it. Nobody  
25 asked me to contribute to that. If it's a way to find

1 a clinical doctor, there are some sites where there  
2 just was two or three bullets about reasons why  
3 somebody might come to the doctor. Anyway, it's  
4 nowhere near complete. Somebody just populated that.

5 Q. Doctor, how many of your articles deal with risk  
6 factors for gynecologic cancer?

7 A. Zero.

8 Q. How many people with ovarian cancer?

9 A. Zero.

10 Q. You have been an expert in many cases. Correct?  
11 How many cases this past year, past 12 months.

12 A. Probably about 15 cases, I'd say.

13 Q. You indicate this is 20 percent of your total  
14 time. That's not 20 percent of your professional  
15 time. It's 20 percent of your time period. Correct?

16 A. 20 percent of the time I do some work.

17 Q. You have testified primarily on issues relating  
18 to lung disease. Correct?

19 A. Correct.

20 Q. You are involved in several cases -- putting  
21 this case aside -- several cases involving  
22 mesothelioma and exposure to talc?

23 A. I don't disagree there have been cases with lung  
24 disease. I don't know if "primarily" is right.  
25 Certainly, there are lung disease cases.

1 Q. Well, let me step back a bit and ask you this  
2 directly, Doctor: The issue we talked about, the  
3 first observational study of ovarian cancer happened  
4 in 1982. From 1982 to now, has Johnson & Johnson or  
5 any talc manufacturer ever come to you and said:  
6 Dr. Diette, I really need your opinion on whether or  
7 not talc causes ovarian cancer?

8 A. No.

9 Q. Even until today, Health Canada came out with  
10 the recommendations we've talked about before, they  
11 had a comment period where they could have people come  
12 in and give comments. Do you understand that to be  
13 true?

14 A. I understand it because your colleague told me  
15 that.

16 Q. You thought that this was such a sloppy work.  
17 Did you ever take the time, given what you have done,  
18 to write a letter and a comment to Health Canada to  
19 say: You know something? You got it all wrong. This  
20 is how you are supposed to look at this question.

21 MS. BROWN: Your Honor, I would object to  
22 counsel's character of Dr. Diette's testimony. He  
23 didn't testify it was sloppy work. I think he has  
24 some critiques of their process, but I would object to  
25 that characterization.

1 MR. TISI: Actually, your Honor, he did at his  
2 deposition, and I can show him. It takes about  
3 5 seconds.

4 THE COURT: It doesn't really matter the words  
5 being used. The real question is, you clearly  
6 disagreed with some of the things they did in their  
7 methods. Did you ever write a letter?

8 THE WITNESS: Other than this matter, I don't  
9 even know who Health Canada is. It is not part of my  
10 business to write them letters about anything,  
11 including this.

12 BY MR. TISI:

13 Q. It is part of your business to be an expert.  
14 Correct?

15 A. In this particular matter. But I honestly don't  
16 know Health Canada. I've never looked up something  
17 about Health Canada.

18 Q. That's interesting, Doctor, because let me ask  
19 you this: Health Canada -- did J&J ever say -- not  
20 J&J's lawyers. J&J the company. Did any scientist at  
21 J&J come to you and say: You know, we have this  
22 comment, period. We need to write to Health Canada  
23 and tell them why they are wrong about their draft  
24 health assessment. Did anybody come to you from the  
25 company and say: Dr. Diette, can you please help us

1 draft something to send to Health Canada, because they  
2 got it all wrong?

3 A. No.

4 Q. Have you ever sought beyond the confines of this  
5 expert report, or whatever expert reports you did in  
6 litigation, to tell people about your opinions of your  
7 colleagues, your professional colleagues, your  
8 regulators, about your views of ovarian cancer and the  
9 talc issue?

10 A. Professional colleagues I've talked to.

11 Q. Did you ever present to anybody, Grand Rounds,  
12 or anything related to this issue?

13 A. I have not given Grand Rounds on this issue.

14 Q. Have you ever given a PowerPoint or a talk about  
15 or anything about ovarian cancer and the risks and any  
16 of the opinions you are prepared to give today?

17 A. No.

18 Q. Let's talk about some basic issues here.

19 Counsel asked you some questions about  
20 hierarchy of evidence. Do you remember those  
21 questions?

22 A. I do.

23 Q. I was a little surprised counsel gave you the  
24 Gordis text because I was going to give you the Gordis  
25 text.

1           You cite the Gordis text for the proposition  
2           that cohort studies are better than case-control  
3           studies, and there is a hierarchy of evidence. Is  
4           that true?

5           A.       I wouldn't agree with "better". I can clarify  
6           my thinking about hierarchy, but I can also wait for  
7           your next question.

8           Q.       Keep going.

9           A.       When we are talking about a hierarchy of  
10          evidence, it exists in terms of the clinical studies,  
11          and there are strata. For example, clinical trials  
12          are considered among the highest quality or highest  
13          tier of studies, the observational studies that are  
14          cohort and case-control belong together, and beneath  
15          those are case reports and case series.

16                 But even within those strata you can still  
17          sort. So there are different kinds of clinical  
18          trials. And so within clinical trials, there are  
19          different types of clinical trials. So you would  
20          place a randomized control trial above a nonrandomized  
21          control trial. And even within that band where you  
22          say clinical trials are higher up than say  
23          observational studies, they are still within that band  
24          of the hierarchy. And so when you get down to  
25          observational studies, generally speaking, cohorts get

1 the nod over case-control, but they do belong in the  
2 same strata.

3 Q. They do belong in the same strata and in fact  
4 Dr. Gordis says they belong in the same strata, don't  
5 they?

6 A. I'm sure he said something approximately like  
7 that.

8 Q. So when counsel put this particular slide up,  
9 nothing in this slide says that cohort studies are  
10 more reliable than case-control studies; they just say  
11 typically they come first. Right?

12 A. If you read it and try to understand it, I think  
13 you will get that, though, because what this says is a  
14 case-control study is useful as a first step. But if  
15 that's all you needed, it wouldn't say the next step  
16 is to carry out a cohort study.

17 So the point here is that there is something  
18 about the cohort study that adds value even when you  
19 have information from the case-control study, and  
20 that's exactly what that so-called real world example  
21 shows, is that there is something to do next.

22 Q. The real world is that case-control studies are  
23 easier to do, they are easier to do, they are less  
24 expensive, and that's why there are more of them.  
25 Correct?

1 A. On average, they are less expensive. They are  
2 certainly more feasible to do time-wise in most cases.  
3 Whether there's more of them, I don't know. In this  
4 matter, that might well be why. But I don't know in  
5 general for the world how they compare.

6 Q. So if scientists are trying to discover an  
7 association or not, the first step is because of  
8 expense and ease is to do a case-control study.  
9 Correct?

10 A. Yes. Just to dial it back, the first step would  
11 be to report a case or a case series to make the  
12 observation and then to try to follow that up with  
13 what's next, and it could be either a case-control  
14 study or a cohort. It often is a case-control if  
15 that's the feasible one to do.

16 Q. Let's look at what Dr. Gordis actually says  
17 about case-control and cohort studies.

18 I have another copy of Dr. Gordis' text. Do  
19 you have that up there, Doctor?

20 A. I did not bring his text with me.

21 Q. On page 257 of his textbook, he has an example  
22 of how you look at studies; does he not?

23 A. We're talking about Table 14-3, which is "The  
24 Process For Using the Evidence and Developing  
25 Recommendations on the Effectiveness of Prenatal



1 Interventions."

2 Q. Correct?

3 MR. TISI: Your Honor, for the record, this is  
4 in your book at plaintiffs' opposition Exhibit 133.

5 THE COURT: Thank you.

6 Q. If you go to the next page, Doctor, he talks  
7 about this as an example. He says:

8 "They thus defined an approach for looking at  
9 causation that may have applicability far beyond  
10 questions of effectiveness of prenatal measures."

11 Do you see that?

12 A. I don't.

13 Q. Do you see that, Doctor?

14 A. I don't know what that sentence means all by  
15 itself. What's they? It says, they thus define --

16 Q. "They" -- the people who have drafted the  
17 process for using evidence to develop recommendations  
18 on prenatal interventions.

19 A. Okay.

20 Q. If you go to this Stage I, and this is really  
21 useful because I think it illustrates what we have  
22 been talking here.

23 If you go to Table 14-3, the first step is  
24 "Categorizing Evidence By Quality and Source."

25 Do you see that?

1 A. I do.

2 Q. And the first is "Trials," and you talked about  
3 that. Correct?

4 A. I did.

5 Q. But even trials can be badly done. Correct?

6 A. Oh, any study can be badly done.

7 Q. So you have to look at the trials. You can't  
8 just throw it in a category because it says  
9 "randomized clinical trial" in front of it. Correct?

10 A. Of course.

11 Q. The second is, "Cohort or Case-Control Studies."  
12 Correct?

13 A. Yes.

14 Q. Underneath it talks about different aspects of  
15 studies that can affect their quality. Correct?

16 A. Sure.

17 Q. At the very bottom it says:

18 "Among other issues that must be considered in  
19 reviewing the evidence are precision of the definition  
20 of the outcome being measured, the degree to which the  
21 study methodology has been described, adequacy of the  
22 sample size, and the degree to which the  
23 characteristics of the population studied and of the  
24 intervention being evaluated have been described."

25 Correct?

1 A. That's correct.

2 Q. The concept they are trying to get through here  
3 is you don't simply put things in a hierarchy because  
4 there is some formula. You have to look at the  
5 attributes of each study and how they were conducted  
6 and whether they were appropriate to answer the  
7 question. Correct?

8 A. Of course.

9 Q. So anybody who would come into court and simply  
10 say, We have a pyramid or a hierarchy, where we put  
11 cohorts above case-control, above case series, above  
12 individual case reports, anybody who does that  
13 mechanically isn't doing their job as an  
14 epidemiologist. Correct?

15 A. You are absolutely incorrect. This is one  
16 table. This doesn't help to define the entire  
17 universe of what my profession does, and I think  
18 invariably clinical trials, as you said, are the  
19 highest tier of evidence, and there's a reason we use  
20 them that way.

21 What you are also saying is that there are  
22 quality issues, which I agree with, that allows the  
23 clinical trial may not inform you as well as a really  
24 good cohort because you may get better data from the  
25 good quality study.

1           Generally speaking, they belong in some order  
2 as you evaluate them. That was the point of the  
3 earlier quote from the same textbook, which is talking  
4 about the sequence of doing studies, that you confirm  
5 what you think you learn from the case control or the  
6 cohort. The next step after that is a clinical trial,  
7 if you can do it. So there is a sequence that makes  
8 sense.

9       Q.     Doctor, you indicated in your expert report --  
10 I'm reading from it, on page 5 -- "cohort studies are  
11 widely regarded as more reliable." You cite Gordis.  
12 There is nowhere in the Gordis text that says that.  
13 Is that true?

14     A.     I didn't quote him.

15     Q.     You did quote him. Actually, if you look at  
16 your footnote here, it goes to footnote 3 of your  
17 report, you cite generally Leon Gordis epidemiology  
18 without a page, footnote 5 on page 5.

19     A.     I think you are confirming what I just said. I  
20 didn't provide a quote. My interpretation from having  
21 this textbook and having been taught from it,  
22 different versions, and using it, is that what I said  
23 is correct.

24     Q.     Doctor, in this big textbook, if this was such a  
25 fundamental principal in this big textbook you used at

1 Johns Hopkins and cited in the Judicial Manual of  
2 Scientific Evidence, if this was a fundamental  
3 principle of epidemiology, don't you think Dr. Gordis  
4 would say that?

5 A. I have no idea what he would have said. I'm  
6 embarrassed we are even having this conversation  
7 because this so baked in what I do for a living, and  
8 what I was taught, and what I teach other people, that  
9 it's not the kind of thing I usually provide a  
10 citation for.

11 Q. Being baked in --

12 THE COURT: There is no quote. I'm not sure  
13 what you were saying.

14 MR. TISI: Well, he's citing to the sentence  
15 as a proposition -- he's citing the proposition there  
16 is a hierarchy of evidence --

17 THE COURT: You said it was in quotes. He is  
18 not quoting anything. I want the record to be  
19 correct.

20 MR. TISI: No quotes, your Honor. The  
21 principle --

22 THE COURT: Let's move on.

23 Q. The next thing I would like to do -- would you  
24 please bring up misconception.

25 Since this is baked in, and you are

1 embarrassed we are having this conversation, do you  
2 know who Ken Rothman is?

3 A. I know of him. I don't know him personally.

4 Q. You are a peer reviewer for the journal  
5 Epidemiology?

6 A. Yes.

7 Q. Do you know Dr. Rothman founded the journal  
8 Epidemiology and was its editor for many years before  
9 he retired from it?

10 A. I do not.

11 Q. Do you know that his textbook is widely used and  
12 cited in the Judicial Manual of Scientific Evidence?

13 A. I don't know what that is.

14 Q. I'm going to show you what has been marked as  
15 Exhibit No. 58. It is an article titled, "Six  
16 Persistent Misconceptions."

17 You have seen this article before. Right?

18 A. I think your colleague showed it to me.

19 Q. Misconception No. 1, could you read it, please?

20 A. (Reading.)

21 "There is a hierarchy of study designs,  
22 randomized trials provide the greatest validity,  
23 followed by cohort studies with case-controls being  
24 least reliable."

25 Q. And if you go down three paragraphs to the very

1 bottom he discusses the issue of case-controls and  
2 cohorts. Do you see that?

3 A. Yes. But you skipped some stuff that would be  
4 important in order to understand that particular  
5 statement.

6 Q. The stuff that's above deals with randomized  
7 control trials. Correct?

8 A. The statement also deals with randomized control  
9 trials.

10 Q. I'm going down to the part that deals with  
11 case-control and cohort studies. It says:

12 "Trials are far from perfect. Furthermore,  
13 both cohort and case-control studies will yield valid  
14 results when properly designed and carried out."

15 Do you see that?

16 A. Yes.

17 Q. Do you agree with that?

18 A. Yes.

19 Q. If you go down to the left-hand column, it says:

20 "Properly designed case-control studies will  
21 produce the same results as properly designed cohort  
22 studies. When conflicts arise, they should stem from  
23 problems with either or both studies."

24 Do you see that?

25 A. I do.

1 Q. He doesn't say if conflicts arise, choose the  
2 cohort?

3 A. You should look at the studies entirely.

4 Q. Exactly. Next quote.

5 "Although case-control studies have long been  
6 disparaged as being backwards versions of cohort  
7 studies, starting from disease and tracing back to  
8 possible causes, epidemiologists today understand  
9 case-control studies to be conceptually identical to  
10 cohort studies, apart from the efficiency gained that  
11 comes from sampling the denominators rather than  
12 conducting a complete census."

13 Did I read that correctly?

14 A. You did.

15 Q. So while you might be embarrassed we are having  
16 this conversation, the idea that you don't simply  
17 elevate cohort studies above case-control studies is  
18 in the epidemiology methods literature. Correct?

19 A. You used a key word which is "simply." I agree  
20 with all the other propositions you put forth which is  
21 you actually have to look at the studies and the  
22 quality of the study. So even if you insisted the  
23 case-control studies and cohorts are exactly on the  
24 same plane, it wouldn't change any of my opinions  
25 about this matter.



1 Q. Next concept is statistical significance. We  
2 talked about that a bit, and let's talk about it  
3 again. I would like to go to Dr. Rothman's textbook  
4 on epidemiology.

5 MR. TISI: Your Honor, it is Plaintiffs'  
6 Exhibit 20.

7 Q. This is Chapter 2 of the book entitled,  
8 "Causation and Causal Inference." Correct?

9 A. I don't know. I'm looking at something else.

10 Q. It is in your binder, sir. The title is "Modern  
11 Epidemiology." The copy of the book is right here.  
12 "Modern Epidemiology."

13 MR. TISI: Your Honor, for the record, it is  
14 cited in the "Judicial Manual for Scientific Evidence"  
15 as one of the references, and that is on Diette  
16 Exhibit 1 -- it is Opposition Exhibit 20.

17 THE COURT: I hope you have permission to copy  
18 the chapter. There is copyright. I'm just noting  
19 that.

20 MR. TISI: Since I'm defending Dr. Rothman --

21 MS. BROWN: Could we make sure Dr. Diette has  
22 a copy of it.

23 THE WITNESS: I have it now.

24 BY MR. TISI:

25 Q. If you go to Chapter 2 entitled, "Causation and

1 Causal Inference," 27, he says -- this is under the  
2 consistency prong of the Bradford Hill criteria. Am I  
3 correct?

4 THE COURT: What page did you say?

5 MR. TISI: 27.

6 Q. Just to orient ourselves, this discusses the  
7 Bradford Hill criteria and how it is taught to  
8 epidemiology students. Correct?

9 A. What it says in this book?

10 Q. Yes. It says "causal criteria" on page 26. The  
11 first category is "strength"; the second category is  
12 "consistency"?

13 A. In terms of getting me to agree with what you  
14 are saying, I don't doubt there are students that use  
15 this. When I took the case-control study course at  
16 Johns Hopkins we used the book called Schlesselman.  
17 So we didn't use this book. I don't know why. I  
18 don't know whether other people use it or not, but  
19 it's not the book I used.

20 Q. On page 27, under the consistency prong, second  
21 paragraph, Dr. Rothman and his colleague,  
22 Dr. Greenland said:

23 "One mistake in implementing the consistency  
24 criterion is so common that it deserves special  
25 mention. It's sometimes claimed a literature or set

1 of results is inconsistent simply because some results  
2 are statistically significant and some are not. This  
3 sort of evaluation is completely fallacious even if  
4 one accepts the use of significance testing methods."

5 Do you see that?

6 A. I do.

7 Q. Do you agree with that?

8 A. I believe we talked about this in my deposition,  
9 that it says that if you do that it says some results  
10 are statistically significant and some are not. I  
11 agree. If that's all you did was line things up and  
12 say these are and these are not, and that's simply  
13 what you did, you would not be done with your  
14 analysis, and I agree with that.

15 Q. So if anybody had done a methodology and simply  
16 sorted by statistical significance and put them in one  
17 bucket on one hand, and nonsignificant results in  
18 another bucket, and then sorted by study design, that  
19 would not be proper methodology. Correct?

20 A. Incorrect. Sorting them into buckets is not the  
21 problem. If we're going to read what he says, he says  
22 to simply do that is a fallacy or it's fallacious. I  
23 agree with that. If you do that and you stop there --  
24 look at the Taher study; they count up how many  
25 studies are statistically significant or not, and they

1 don't stop there either. They are not wrong to  
2 describe the studies as being statistically  
3 significant or not. They would be wrong if they only  
4 did that. That's how I read this.

5 Q. The way you read it is in the context in which  
6 it is written. It is written under the section  
7 involving consistency of association. Correct?

8 A. I'm reading this under the context of how it is  
9 written? Well, of course.

10 Q. It is written in the section that deals with  
11 consistency. Correct?

12 A. Exactly.

13 Q. And so what we're trying to figure out, are  
14 studies consistent. Correct?

15 A. Are studies consistent?

16 Q. Yes, are multiple studies, when you line them  
17 up, are they consistent?

18 A. It says that if you simply do that, that you  
19 have done something wrong.

20 Q. And do you agree with that?

21 A. If that's all you do.

22 Q. The next thing I want is to show you another  
23 textbook from Dr. Oleckno, and that is Opposition  
24 Exhibit 1, 43. I would ask you to go to page 222.

25 MS. BROWN: Counsel, is that in the binder you

1 gave me?

2 MR. TISI: It is in the binder. It is  
3 Exhibit 143.

4 Q. On the left side on page 222 it says the  
5 following:

6 "Finally, statistically significant is often  
7 misinterpreted as meaning that the null hypothesis is  
8 false or that the association is one of cause and  
9 effect. Neither can be demonstrated using statistical  
10 significance testing, which depends on probabilities.  
11 For these and other reasons most epidemiologists  
12 prefer to use confidence intervals."

13 Do you see that?

14 A. I do.

15 Q. Do you agree with it?

16 A. I'm still trying to figure out what this is. I  
17 don't know who Oleckno is.

18 Q. Your colleague, Dr. Merlo, who is also an expert  
19 in this case relied on this textbook. You know who  
20 Dr. Merlo is. Right?

21 A. I do.

22 Q. Dr. Merlo, who is one of the other epidemiology  
23 experts whose opinions they are challenging, has  
24 relied on this textbook.

25 A. I don't doubt you. I just don't have any idea

1 who this is.

2 Q. Well, do you agree with the principle most  
3 epidemiologists look to confidence intervals rather  
4 than just simply deciding whether or not something is  
5 statistically significant or not?

6 A. So I think most epidemiologists look at both of  
7 those things, but you have to understand that they are  
8 complimentary. It's not as if one versus the other.  
9 A 95 percent confidence interval is the equivalent of  
10 establishing what a P of less than .05 is.

11 I think the way I have been hearing the  
12 conversations go about this matter, there seems to be  
13 some confusion about that. But if the P is less than  
14 .05, the 95 percent confidence interval is going to  
15 include 1. So they are basically redundant in one  
16 way, but they tell you some complimentary information  
17 about the significance.

18 Q. So you look at it all?

19 A. Of course.

20 Q. When Dr. McTiernan was here yesterday, one of  
21 the things she said was that you just don't simply  
22 look at whether or not the lower bounds of the  
23 confidence interval crosses 1. She says you look at  
24 it all. You look at where the confidence intervals --  
25 how tight they are, where the point estimates are, and

1 how they line up. You remember that testimony.

2 Correct?

3 A. I do.

4 Q. That's the way epidemiologists look at it.

5 Correct?

6 A. You look at all of those things. That doesn't  
7 mean you can reach the conclusion that you are going  
8 to reach just by doing that.

9 Q. What you don't do is, you don't ignore  
10 everything that happens on the right-hand side of the  
11 null value and only see are there studies that cross 1  
12 and then collapse it to only deal with the cohort  
13 study?

14 A. I think in almost any question you asked, if you  
15 say you only do something, I'm going to disagree with  
16 you. If you say you do something, I may well agree  
17 with you. You certainly may look at whether or not  
18 the confidence interval includes 1, and you should use  
19 that to inform something about what the information is  
20 telling you. You should also do what you said which  
21 is to also look at the confidence interval and how  
22 wide it is. Those are both things that you do.

23 Q. At the end of the day, one of the things you  
24 have to do is you exercise your professional judgment  
25 to try to decide what this all means. Correct?

1 A. Yes, although there is not information enough  
2 information on that particular slide to reach the  
3 conclusion whether or not there is causation.

4 Q. I didn't say that, Doctor. We're talking about  
5 it in context of consistency of association. One of  
6 the things we talked about is: Are these results  
7 consistent? What you don't do is you don't block off  
8 what is to the right of the null value and then sort  
9 them by study design.

10 A. I agree that you don't simply do that. Each  
11 time you say "only" it suggests something. But if all  
12 of those values that we saw on that forest plot were  
13 all well to the right of the line of unity, that one  
14 line, that would tell us something. If they were all  
15 completely to the left, that would tell us something.  
16 If there is a mixture, that tells us something. So  
17 you do look at it. But how you reach your conclusion  
18 about causation doesn't come from just looking at  
19 that.

20 Q. But one of the things you have to do when you do  
21 look at this is to exercise your judgment and try to  
22 decide what this all means?

23 A. That's part of the picture.

24 Q. Now, the other thing you said, and you asked and  
25 I wrote this down when J&J's lawyer asked you, you



1 said confidence interval crosses 1 means no  
2 association. Is that true?

3 A. That's what we were reading from that article.

4 Q. But that is not true, is it? When it crosses 1,  
5 you can't make any decision about association.  
6 Correct?

7 A. Incorrect. That's why I brought that article,  
8 because it comes from a current good journal, from the  
9 Nurses' Health Study, and because those authors used  
10 the conventions that those of us who publish papers  
11 and write grants have to use when we communicate with  
12 people.

13 Q. Doctor, let me bring up Exhibit 142, please.

14 Are you familiar with the American Statistical  
15 Association?

16 A. Barely. I've heard of them, and I've heard the  
17 most I've ever heard in my life from you guys.

18 Q. Do you know whether or not Dr. Ballman was an  
19 officer -- one of your co-experts for J&J was an  
20 officer of the American Statistical Association?

21 A. I don't know.

22 Q. Let me see if we could go to the next page.

23 It is the American Statistical Association's  
24 statement on p-Values, Content, Process and Purpose.

25 Do you see that?

1 A. Yes.

2 Q. One of the things -- I want to go through this  
3 very briefly.

4 On the left-hand side at the bottom it says:

5 "The ASA Board decided to take up the  
6 challenge of developing a policy statement on p-Values  
7 and statistical significance, it did so recognizing  
8 this was not a lightly taken step."

9 Do you see it?

10 A. I do.

11 Q. First of all, you are not a statistician or  
12 biostatistician; are you?

13 A. I don't hold myself out that way, but  
14 biostatistics is part of my training and part of the  
15 tool set that I use in my work.

16 Q. Next column, second paragraph, this is by  
17 contrast:

18 "The Board envisioned that the ASA statement  
19 on p-Values and statistical significance would shed  
20 light on an aspect of our field that is too often  
21 misunderstood and misused in the broader research  
22 community and in the process provides the community a  
23 service."

24 Do you see that?

25 A. I do.

1 Q. (Reading.)

2 "The intended audience would be researchers,  
3 practitioners, and science writers who are not  
4 primarily statisticians. Thus, this statement would  
5 be quite different from anything previously  
6 attempted."

7 Do you see that?

8 A. I do.

9 Q. This was the first and only time the American  
10 Statistical Association ever took the step to make a  
11 comment on a statistical matter.

12 Do you understand that to be true?

13 A. I don't know. It's interesting.

14 Q. Next page.

15 "The people who are involved in this process"  
16 -- if you go on the left-hand side.

17 Do you know who Jim Berger is and Steve  
18 Goodman?

19 A. I know Steve Goodman.

20 Q. He is at Johns Hopkins; isn't he?

21 A. Not anymore.

22 Q. Was he?

23 A. He was.

24 Q. Good researcher?

25 A. Yes. I think so.

1 Q. Now, one of the things attached to this  
2 editorial is the ASA statement on statistical  
3 significance and p-Values.

4 Do you see it?

5 A. I do.

6 Q. Then if you go to the second paragraph on the  
7 introduction, it says:

8 "Underpinning many published scientific  
9 conclusions is the concept of statistical  
10 significance, typically assessed with an index called  
11 p-Value."

12 Do you see that?

13 A. I do.

14 Q. (Reading.)

15 "While the p-Value can be a useful statistical  
16 measure, it is commonly misused and misinterpreted."

17 Do you see that?

18 A. I do.

19 Q. The next paragraph, it says, second sentence:

20 "The issues touched on here affect not only  
21 research, but research funding, journal practices,  
22 career advancement, scientific education, public  
23 policy, journalism, and law."

24 Do you see that?

25 A. I do.

1 Q. Let's go to the second statement that the ASA  
2 makes on statistical significance. It says:

3 "P-Values do not measure the probability that  
4 the studied hypothesis is true or the probability that  
5 the data were produced by random chance alone."

6 Do you see that?

7 A. I do.

8 Q. Do you agree with that?

9 A. I do.

10 Q. (Reading.)

11 "Researchers often wish to turn to a P-Value  
12 into a statement about the truth of the null  
13 hypothesis or about the probability that random chance  
14 produced the observed data. The p-Value is neither.  
15 It is a statement about the data in relation to a  
16 specified hypothetical explanation and is not a  
17 statement about the explanation itself."

18 Do you see that?

19 A. I do.

20 Q. Do you agree with that?

21 A. There is a lot there. It depends upon the  
22 context for this. When you say -- if you want to turn  
23 it into a statement about the truth of a null  
24 hypothesis, it's not literally that. It's the chance  
25 you are willing to take to get the wrong answer. So a

1 lot of this I think is very confusingly described by  
2 people, but these particular words I agree with them.

3 Q. The next point is:

4 "Scientific conclusions and business or policy  
5 decisions should not be based on whether p-Value  
6 crosses a specific threshold. Practices that reduce  
7 data analysis or scientific inferences to a mechanical  
8 bright line rule such as p-Value less than .05 for  
9 justifying scientific claims or conclusions can lead  
10 to erroneous beliefs and poor decision-making. A  
11 conclusion does not immediately become true on one  
12 side of the divide or false on the other."

13 Do you see that?

14 A. I do.

15 Q. Do you agree with it?

16 A. Generally speaking, you can reach the wrong  
17 conclusion. But I would say every single drug that  
18 you and I take that has been approved by the FDA  
19 requires a p-Value of less than .05. Even if you  
20 philosophically disagree with hypothesis testing or  
21 some of the principles, this is the world we live in.

22 Q. Doctor, drug approval is a different issue than  
23 we're facing here. We are trying to decide whether or  
24 not the epidemiologic data on balance supports a  
25 conclusion that there is an association and a

1 consistency --

2 A. It is not at all a different issue. It is a  
3 different application. It's the same topic and the  
4 same topic is if you set up a hypothesis and test it,  
5 do you accept or reject the hypothesis?

6 My point is the FDA may be doing something  
7 that is imperfect, but that is the world we live in.  
8 That JAMA article we looked at earlier today, JAMA  
9 Oncology, their editors and the authors may be doing  
10 something imperfect, but that's the world we live in.  
11 If you want to report your results those are the rules  
12 you use right now.

13 Q. We're not talking about reporting the results.  
14 We're talking about interpreting the results.

15 Let me ask the question. I'm trying to get  
16 from you not about publishing an article, not about  
17 getting a drug approved. I'm asking you a question.

18 We're looking at a series of studies and  
19 trying to decide whether or not those studies, taken  
20 in the aggregate, favor an association and a  
21 consistency of association.

22 A. What you are showing me --

23 Q. There is no question pending. Let me ask you  
24 the question.

25 My question now is: Isn't it important to

1 look at the totality of the data, including confidence  
2 intervals, including p-Values, including the risk  
3 estimates, look at it all and see what patterns arise?

4 A. I already said that I agreed with you when you  
5 asked me that before.

6 Q. So you don't simply say: You know, it crosses  
7 the line, no association?

8 A. In which case?

9 Q. In the case of multiple studies. If you have  
10 multiple studies side-by-side, one having crossing 1  
11 and all the others not crossing 1, you wouldn't say  
12 that was not an association. Correct?

13 A. I think you are either misunderstanding  
14 something or you are trying to be confusing.

15 First of all, I don't think the authors of  
16 that paper misstated it when they said there was no  
17 association when they reported that, and it is the  
18 same hypothesis testing principle that's used when you  
19 combine studies into one.

20 For example, the meta-analysis we looked at,  
21 the meta-analyses combine a pooled estimate, and they  
22 provide a p-Value based on the same principle of  
23 hypothesis testing. We looked at that forest plot.  
24 It tells you something. It doesn't tell you  
25 everything. And these things we're looking at here



1 don't tell you what to do in this circumstance.

2 Q. Doctor, right after you filed your expert  
3 report, the American Statistical Association came out  
4 with a journal with 42 articles dealing with this very  
5 issue, did it not?

6 A. It did.

7 Q. And it devoted the entire journal to this issue  
8 because of what it described as a serious problem with  
9 the use or the misuse of statistical significance.  
10 Correct?

11 A. That was one of the motivations.

12 Q. And one of the articles that came out of that,  
13 an editorial that I'm going to show you. It is  
14 Exhibit 13.

15 Doctor, I placed in front of you, this is  
16 Diette Exhibit No. 13. This is an article that  
17 accompanied those 42 articles, but it happened to  
18 appear in the journal Nature.

19 Do you see it?

20 A. I do.

21 Q. It is signed by, among others, Sander Greenland.  
22 Correct?

23 A. That's correct.

24 Q. Dr. Greenland is the co-author on the book of  
25 epidemiology that we talked about before. Is that

1 correct?

2 A. That's correct.

3 Q. And Sander Greenland you know within a week of  
4 this being circulated, 800 statisticians and different  
5 researchers and epidemiologists signed onto this.

6 Correct?

7 A. I think that's correct.

8 Q. And it was widely circulated including amongst  
9 the Johns Hopkins community. Correct?

10 A. You showed me -- your colleague showed me  
11 something from our ICTR website that showed that it  
12 had been posted there.

13 Q. If anyone were to describe Dr. Rothman and  
14 Dr. Greenland and any of these people as outliers,  
15 would that be accurate?

16 A. In what way?

17 Q. Pariahs in the epidemiology community?

18 A. That's not a term I use. There is no reason to  
19 disparage them.

20 Q. Okay. Now, in this article they describe what  
21 they call a pervasive problem, and they say:

22 "Let's be clear about what must stop: We  
23 should never conclude that there is no difference or  
24 no association just because a p-Value is larger than a  
25 threshold such as .05 or equivalently because a

1 confidence interval includes zero."

2 Do you see that?

3 A. I do.

4 Q. "Neither should we conclude that two studies  
5 conflict because one has a statistically significant  
6 result and the other does not. These errors waste  
7 research testify efforts and misinform policy  
8 decisions."

9 Do you see that?

10 A. I do.

11 Q. Do you agree with the authors that you should  
12 not -- epidemiologists must not say that studies  
13 conflict because one has a statistically significant  
14 result and the other one does not?

15 A. I don't automatically agree with that. I think  
16 you have to look at the context for this. I think you  
17 showed me this is an editorial in a different journal  
18 from Nature, which if you look at the exact same  
19 journal issue, you will see that they provide  
20 instructions to the authors on how to report their  
21 p-Values and how to report their confidence intervals.  
22 These are interesting ideas you are presenting. I'm  
23 not sure whether it is going to be the Court's job to  
24 decide whether or not this has taken hold.

25 But I can tell you that in the current world I

1 work in of epidemiology and medicine we rely on  
2 p-Values, we rely on 95 percent confidence intervals,  
3 and I can't send a paper to a publication and say: By  
4 the way Sander Greenland said I shouldn't be doing  
5 this, so I don't want you to look at this.

6 Q. Do you understand that we are suggesting you  
7 jettison any concept of statistical significance?

8 A. I can't tell what you're suggesting that you're  
9 not saying now.

10 Q. What he's saying here is you don't misuse it.  
11 You don't conclude the two studies conflict because  
12 one is statistically significant and one is not.

13 A. It also says that you shouldn't use a p-Value  
14 threshold such as .05. Unfortunately, that's the  
15 world we live in. To me this is like if you decided a  
16 jury trial of 12 people is the wrong way to do law.  
17 Maybe there is a better way. But I assume at the  
18 moment you use 12 people in the jury pool.

19 This is the same thing. There could be a  
20 better way, but at the moment these are not the rules  
21 of the game. These are somebody's opinion about what  
22 might happen.

23 Q. Doctor, if you go back to the American  
24 Statistical Society's statement, you have articles  
25 going back to the 1960s that support the misuse. You

1 can take a look at it. There are footnotes here going  
2 back to the 1960s and '70s talking about that  
3 epidemiologists should not do what you are doing.

4 A. No. What I told you earlier -- at least I've  
5 told the Court earlier -- was this is an issue we have  
6 been discussing ever since I have been in this field.  
7 This is over 20 years. It is a very interesting  
8 issue, and it may at some point change.

9 You are cherry-picking a few quotes that are  
10 opportunistic here. But if you read the entire  
11 introduction to that journal you are talking about,  
12 you are going to see a lot of different opinions  
13 including questions like: Are we suggesting that we  
14 abandon P-Values? And they say no, and they go on and  
15 on and say: Well, what should the substitute be?  
16 There are at least seven or eight major ideas of what  
17 the substitute should be and they have not been  
18 endorsed yet.

19 Q. I really need you to focus on what I'm asking.  
20 I'm asking, using statistical significance to define  
21 consistency. I'm not asking you to publish a paper.  
22 I'm not asking you to get a drug approved. I'm not  
23 asking you what it takes to get a paper published.  
24 I'm asking you how do you interpret the results when  
25 you're combining studies together.

1           So if you would stay focused on that, I'm  
2 going to ask you a question.

3           The next question goes to the next page. They  
4 have a statement here that says:

5           "Beware of false conclusions."

6           If you look at the chart, they give a generic  
7 example, and the generic example are two studies: One  
8 study they are keeping the point estimate exactly the  
9 same. Correct?

10          A.       That's correct.

11          Q.       One study has a tight confidence interval not  
12 crossing 1?

13          A.       That's correct.

14          Q.       The other one has a longer confidence interval  
15 crossing 1?

16          A.       That's correct.

17          Q.       And it would be wrong to say you look at this  
18 little tail right here and say that these two studies  
19 are inconsistent because this study crosses 1.  
20 Correct?

21          A.       Well, there is obviously some difference in  
22 those studies, and one has greater variability than  
23 the other. They both have the same point estimate but  
24 you wouldn't look at those and say they are identical  
25 because they are not.

1 Q. Consistency doesn't imply you have to have  
2 identical studies results. How often does that  
3 happen?

4 A. Still, there is an inconsistency here.

5 Q. But to say that these two studies are  
6 inconsistent for the purpose of a Bradford Hill  
7 analysis, are you saying these two studies are  
8 inconsistent?

9 A. They might or might not be. I would say more  
10 than just what you have on the slide there. But what  
11 I would say is that if you looked at my slide from  
12 earlier today, I'm not saying the entire consistency  
13 criterion is fulfilled by whether things are  
14 statistically significant or not. What I really  
15 focused on primarily was that the different designs  
16 produce different answers, and it is not because of  
17 something that looks like that. It's because there is  
18 a null effect from the cohort studies and not the  
19 case-control.

20 The one up top would not be a good description  
21 of the average case-control effect and the bottom the  
22 average cohort effect. You have to move the red dot  
23 way, way, way to the left, almost to the line of 1  
24 there.

25 Q. Doctor, when you were using the example with

1 J&J's counsel, you were talking about one study, and  
2 you talked about how wonderful the study was. Do you  
3 remember that?

4 A. I did.

5 Q. What we are talking about here is, not  
6 evaluating internally one study but comparing studies  
7 across a continuum of 40 years in multiple countries,  
8 multiple researchers, multiple different designs.  
9 Correct?

10 A. Correct.

11 Q. And so when you are comparing studies as opposed  
12 to looking internally within a study, you have to have  
13 some metric to kind of understand what those studies  
14 are telling you. True?

15 A. Some metrics help.

16 Q. What you are doing, what I think you are saying  
17 is if it's statistically significant -- I wrote this  
18 down -- counsel wrote it down. If it's 1, it's no  
19 association; and if it is no association, it is  
20 inconsistent with a study that shows a positive  
21 association.

22 Is that what you are saying or not?

23 A. That's literally what that study language was.

24 Q. And what I'm asking you, is: Are these 800  
25 statisticians and the people at the American



1 Statistical Association, you have one study and you  
2 have a consensus statement, what are we to make of  
3 that, Doctor?

4 A. There is no consensus statement. There are 800  
5 people who signed onto the proposition we should look  
6 into this and consider this. If you read the entire  
7 front end of that document from the statistical  
8 association, you will see lots of good ideas in there,  
9 and it is not a prescription for what to do. It's a  
10 call for considering potentially other ways of doing  
11 business.

12 Q. Doctor, they are not saying this is a call for  
13 what not to do. Back up to the prior page.

14 They are not saying what they are calling not  
15 to do. They are saying, let's be clear about what  
16 must stop.

17 A. You are reading from a different document.

18 Q. Doctor, wouldn't you agree with me, when you go  
19 back and take a look at the studies, that you have to  
20 use people like you and Dr. McTiernan,  
21 Dr. Siemiatycki, and Dr. Merlo, they have to use their  
22 own judgment when looking at this plot. There is no  
23 mechanical way of doing it.

24 Is that true when you look at the forest plot?  
25 If it were that easy, people like me could do it. You

1 have to use your professional judgment to make that  
2 call. True?

3 A. Make which call?

4 Q. About whether or not this is a consistent  
5 association.

6 A. Well, if you use your professional judgment  
7 correctly, you should look at those ones below that  
8 heavy horizontal line that says "cohort studies." You  
9 should remove two of the bottom three because that's  
10 redundant. It's representing a single study three  
11 times to make it look as if there are five different  
12 results. There are not.

13 You would take the most recent one which is  
14 the Gates one at the bottom. You would keep Gonzalez  
15 and you would keep Houghton, and I think you would  
16 reach a conclusion that those are consistently  
17 approximately null, which is exactly the same thing  
18 that the meta-analyses say when they analyze the  
19 cohort studies by themselves.

20 Q. And the reason why you say that is because in  
21 your mind case-control studies are inferior by design  
22 to cohort studies and some of these results cross 1.  
23 Correct?

24 A. No, you are incorrect. The reason I'm saying it  
25 is because that slide is misleading; and if we are

1 looking for consistency that I was talking about  
2 earlier, it is the consistency by study design.

3 So regardless of what you think you know about  
4 the ones that are all above that horizontal line,  
5 there is an inconsistency between what you see up  
6 above that line and what you see down below that line,  
7 especially when you remove the misleading two extra  
8 bars there.

9 Q. I want to turn my attention to the bias issue  
10 that you talked about before. It's on page 19 of 20  
11 of your report. The study that you rely on, I tried  
12 to write it down, and you said it's a teaching study.  
13 It's the kind of study you would take and you are  
14 going to teach people about the issue of recall bias.

15 Do you remember that?

16 A. I do.

17 Q. It's the Schildkraut study?

18 A. It is.

19 Q. And the Schildkraut study actually was written  
20 by one of plaintiffs' experts, Dr. Moorman?

21 A. Correct.

22 Q. Your opinions on recall bias are on page 19 or  
23 20. The study that you primarily rely on is the  
24 Schildkraut study. Correct?

25 A. Yes.

1 Q. And that's the study you told counsel is the one  
2 you would use as a teaching study?

3 A. Absolutely.

4 Q. About recall bias. Correct?

5 A. Without a doubt.

6 Q. And if you look at what Schildkraut said --  
7 let's go to Schildkraut.

8 MR. TISI: It's Exhibit No. 8, your Honor.

9 Q. Let's just orient ourselves to what the study  
10 actually said.

11 This is the Schildkraut study, and it's titled  
12 the "Association Between Body Powder Use and Ovarian  
13 Cancer," and this is from the AACES. Correct?

14 A. Yes.

15 Q. Dr. Moorman is the last author which means she  
16 is the senior author on the paper?

17 A. Sometimes it does.

18 Q. The results of the study as listed above is  
19 powder use was common 62 percent of cases and  
20 52 percent of controls. Genital powder was associated  
21 with an increased risk of epithelial ovarian cancer,  
22 odds ratio 1.44, and a dose-response relationship was  
23 found for duration of use and number of lifetime  
24 applications.

25 Correct?

1 A. That's correct.

2 Q. This is one of those studies that found an  
3 association and found dose-response?

4 A. In the combined pre-and-post 2014.

5 Q. And if you look at the last page -- before we  
6 talk about recall bias -- if you go to the last page,  
7 page 1416, it says:

8 "The results of the current study showed that  
9 genital powder use was associated with ovarian cancer  
10 risk in African-American women and are consistent with  
11 localized chronic inflammation in the ovary due to  
12 particulates that travel through a direct transvaginal  
13 route."

14 Do you see that?

15 A. I do.

16 Q. It's talking about biologic plausibility and  
17 association Correct?

18 A. Correct.

19 Q. "The dose-response observed for duration of  
20 genital powder use provides further evidence for the  
21 relationship between genital powder use and overall  
22 EOC risk. Our data suggest that the increased risk  
23 due to genital powder applies to both serous and  
24 nonserous histological subtypes of EOC?"

25 Do you see that?

1 A. I do.

2 Q. First of all, you know that Dr. Moorman was not  
3 our expert when she wrote this?

4 MS. BROWN: Objection, your Honor. How in the  
5 world would he know that.

6 Q. You read her deposition, haven't you?

7 A. If I did, I don't remember that fact.

8 THE COURT: Okay. Let's move on.

9 Q. Now, the issue of recall bias was addressed by  
10 her using the very data that you say is exemplary of  
11 the issue. Correct?

12 A. It is.

13 Q. And if you look at the chart, and I think the  
14 chart you referred to is chart Table II. It shows a  
15 differentiation between pre-and-post-2014 recall. Is  
16 that correct?

17 A. Or reporting.

18 Q. Or reporting.

19 Now, Dr. Schildkraut addressed that finding --  
20 the Schildkraut authors addressed that finding; did  
21 they not?

22 A. They discussed it.

23 Q. And if you go to page 1416, it says, last page  
24 of the narrative, on the right-hand side:

25 "The authors state: Although our findings

1 suggest that the publicity of the class action  
2 lawsuits may have increased reporting of body powder  
3 use, our data do not support that recall bias before  
4 2014 versus 2014 or later, which would account for the  
5 association with body powder use and EOC. It is  
6 possible that the lawsuits sharpened the memories of  
7 body power use and improved the accuracy of reported  
8 use for both cases and controls interviewed in 2014 or  
9 later."

10 Correct.

11 A. That's correct.

12 Q. She makes two observations: No. 1 is, this  
13 finding doesn't incriminate in any way the study that  
14 came before 2014. Correct?

15 A. I think this is an extrapolation from their own  
16 data. This is a current era study. They can't  
17 comment from this study based on what was true  
18 earlier.

19 Q. I'm asking you what they said.

20 A. I'm answering what I think they mean because  
21 that's the way I heard you. We just read the  
22 statement.

23 Q. Do you want to see what Dr. Moorman means about  
24 that?

25 A. Not particularly. I think this is a really

1 interesting study. They provide a really good  
2 rationale for looking for an interaction. They  
3 demonstrate an interaction which you just showed in  
4 Table II. They calculated the p-Value for whatever  
5 reason and showed that interaction was significant.

6 So it shows one of the clearest examples I  
7 have seen, and the only one in this particular matter,  
8 where there is evidence of recall bias within a  
9 particular study.

10 MR. TISI: Your Honor, permission to play a  
11 very brief video clip, about 30 seconds on this issue.

12 THE COURT: On which issue?

13 MR. TISI: On the issue of recall bias.

14 THE COURT: I'm not sure why we are doing  
15 that.

16 MR. TISI: I want to ask him whether or not he  
17 agrees or disagrees about what she said about her own  
18 study.

19 MS. BROWN: Your Honor, I would object. No.  
20 1, I'm not sure what the relevance of that is. No. 2,  
21 there is no foundation he is even aware of that and  
22 certainly has no impact on his opinion. So I would  
23 object on lack of foundation and relevance.

24 MR. TISI: Your Honor, he spent a lot of time  
25 discussing her study, A. B, he spent a lot of time



1 criticizing her, and half of his report is spent  
2 criticizing the methodology of the plaintiffs'  
3 experts. I think hearing from what a witness for  
4 30 seconds --

5 THE COURT: I'm not sure when you have a 30-  
6 second clip, I have a problem with what was said  
7 before and what was said later. That's a problem I  
8 have. So I don't think that's going to be useful. So  
9 let's move on. There is plenty of briefing on Dr.  
10 Moorman, too.

11 BY MR. TISI:

12 Q. Doctor, counsel asked you questions about IARC  
13 and whether IARC addressed the issue?

14 A. Which issue?

15 Q. The issue of bias, recall bias.

16 Do you remember counsel for J&J asking you  
17 whether IARC addressed the issue of whether recall  
18 bias affected the case-control studies?

19 A. Yes.

20 Q. In fact, that was not a complete reading of what  
21 IARC actually said, was it?

22 A. It's a very long monograph.

23 Q. It's not even a complete statement of what they  
24 said about recall bias; was it?

25 A. Let's have a look.

1 Q. Let's have a look.

2 Would you please go to Exhibit 57 in your  
3 booklet, page 409. Why don't we address all of the  
4 things IARC addressed here because it addresses bias,  
5 chance, and confounding, all three things. I intend  
6 to discuss them differently so we don't have to go  
7 back to the document.

8 IARC 2010 publication says the following --  
9 explain for the record what IARC is. IARC has pulled  
10 together all the studies and looked at this issue --

11 THE COURT: Do you want him to explain it or  
12 do you want to explain it?

13 MR. TISI: I apologize.

14 Q. You understand that IARC looked at this issue in  
15 2006?

16 A. I do.

17 Q. You understand they aggregated all the studies  
18 that were then available?

19 A. I do.

20 Q. You understand those results were actually  
21 published in 2010 and that's what we are looking at  
22 now. Correct?

23 A. That's what I understand.

24 Q. The first thing they looked at were some of the  
25 issues you described: Could chance explain these

1 observations or results?

2 "First, while chance cannot be ruled out as an  
3 explanation, it seemed very unlikely to be responsible  
4 for the consistent pattern of excess risks."

5 Do you see that?

6 A. Yes.

7 Q. First of all, they call it "consistent,"  
8 correct, a consistent pattern?

9 A. Correct.

10 Q. When they talk about the risk, they talk about  
11 it in terms of consistency. Correct?

12 A. Correct.

13 Q. Next sentence:

14 "A second possible explanation would be recall  
15 bias, to which case-control studies may be  
16 particularly susceptible."

17 See that?

18 A. Yes.

19 Q. (Reading.)

20 "This may have been the case had there been  
21 wide spread publicity about the possible association  
22 between the use of body powder and cancer. In such  
23 circumstances, it is possible that women who had  
24 ovarian cancer could be more likely than women who did  
25 not to remember or over-report a habit, such as body

1 powder use, if they thought that it may have played a  
2 role in their illness."

3 Did I read that correctly?

4 A. You did.

5 Q. (Reading.)

6 "There was a flurry of publicity in the U.S.A.  
7 in the mid 1970s concerning the possible risks of  
8 cancer posed by the use of talc body powders.  
9 Following industry decision to market talc powders  
10 with no asbestos, it was the opinion of the working  
11 group that there had not been widespread public  
12 concern about this issue, at least until relatively  
13 recently. Therefore, the working group considered it  
14 unlikely that a bias could explain the set of  
15 consistent findings that stretch out over two  
16 decades."

17 Do you see that?

18 A. Yes. Would you mind just finishing.

19 Q. I am.

20 "The group believed that recall bias was  
21 possibly inherent in the case-control studies and  
22 could not rule it out."

23 That's the sentence your counsel provided to  
24 you. Correct?

25 MS. BROWN: Objection, your Honor. That's

1 incorrect. The IARC sentence we put out was the  
2 definition of 2-B. It was not this. So I would  
3 object to any suggestion we were somehow  
4 misrepresenting that.

5 THE COURT: All right.

6 BY MR. TISI:

7 Q. Let's look at what they actually said. They  
8 said:

9 "The working group considered it unlikely that  
10 such a bias in the context of talc and ovarian cancer  
11 was the explanation."

12 Did they not say that?

13 A. They said both that and that it was a  
14 possibility.

15 Q. It always is a possibility. In fact, Dr. Gordis  
16 addresses that in his book, but he says it almost  
17 never happens; doesn't he?

18 A. To the contrary. He actually provides excellent  
19 examples.

20 Q. Let's go to his book, if you have it in front of  
21 you.

22 THE COURT: Mr. Tisi, you have a half hour  
23 left.

24 MR. TISI: I'm going to move on, your Honor.

25 Q. Let's talk about that confounding.

1 IARC also addressed the issue of confounding;  
2 did it not?

3 A. It did.

4 Q. If you go to page 408 of the 2010 IARC report,  
5 it says --

6 MR. TISI: For the record, your Honor, that is  
7 Exhibit 8.

8 Q. It says:

9 "It is possible that confounding by  
10 unrecognized risk factors may have distorted the  
11 results. One or more factors, if they are causes of  
12 ovarian cancer and also associated with the population  
13 of perineal use of talc, could induce the appearance  
14 of an association between the use of talc and ovarian  
15 cancer where there is none."

16 Do you see that?

17 A. I do.

18 Q. "In order for such an unrecognized risk factor  
19 to induce the consistent pattern of excess risk in all  
20 the case-control studies, it would be necessary for  
21 the factor to be associated with perineal talc use  
22 across different countries in different decades."

23 That's the issue I raised before. Correct?  
24 You would have to show the confounder in the case we  
25 are talking about here with douching, it would have to

1 be a pattern of use that would be the same in other  
2 countries, in different decades, and under different  
3 circumstances than it was in the Nurses Health Study,  
4 in the Sister Study. Correct?

5 A. You would have to show it was different?

6 Q. You would have to show it was the same.

7 A. No. If you wanted douching to be the only  
8 example, you would have to show that that was also  
9 present.

10 Q. I'm talking about douching now.

11 A. I missed that. I thought we were talking about  
12 here in general about confounders.

13 Q. If douching was an issue, a true confounder, it  
14 would have to be an issue that was associated with  
15 talc use, not only in the sister study, but in every  
16 study in every country in every decade in which this  
17 issue was studied. True?

18 A. No, it wouldn't.

19 Q. Doctor, isn't that what IARC is saying here:

20 "It would be necessary for the factor to be  
21 associated with perineal talc use across different  
22 countries and different decades to be a true  
23 confounder in this circumstance"?

24 A. They are saying that. But what I'm saying is  
25 that douching would not have to be the confounder, and

1 it wouldn't have to be present in all of those other  
2 studies.

3 Q. You can't say to a reasonable degree of medical  
4 scientific certainty; and, in fact, you don't know  
5 that confounding explained the risks of ovarian cancer  
6 and talc in studies. True? You say it could and it  
7 may?

8 A. That I agree with.

9 Q. But you don't say that it does; do you?

10 A. No, most of the risks of ovarian cancer isn't  
11 known and so most of the risk has not been accounted  
12 for in any of the studies.

13 Q. Just to be clear, you cannot say to a reasonable  
14 degree of medical certainty that douching is a  
15 confounder for the ovarian cancer study; can you?

16 A. I cannot say that it is, correct.

17 Q. And you cannot say any of the factors that you  
18 discussed -- you cannot say that confounding is a  
19 factor that in your opinion to a reasonable degree of  
20 medical certainty affected the results of these  
21 studies; can you?

22 A. I think that genetic susceptibility likely did,  
23 but I can't prove it to you.

24 Q. Going back to the issue of recall bias, your  
25 report is very clear that recall -- that you say it



1 could affect. You are not telling the Court that to a  
2 reasonable view of medical certainty based upon your  
3 review of the entirety of the data that recall bias  
4 was the explanation for the increased risk in the  
5 case-control studies, are you?

6 A. I can't say it has to be. I can say it's  
7 demonstrated in the one study affirmatively.

8 Q. It's demonstrated in one study from 2014  
9 forward, in that one study?

10 A. True.

11 Q. And most of these studies we are talking about  
12 preceded 2014. Correct?

13 A. And didn't examine the issue.

14 Q. Let me ask you this, Doctor: On the recall bias  
15 issue, you provided appendix A to your report, which  
16 was a list of articles in a public media about talc  
17 and ovarian cancer, and you used that to illustrate  
18 the possibility prior to 2014 there may have been  
19 publicity in some of these -- may have been publicity  
20 that may have affected some of these women. Correct?

21 A. That's correct.

22 Q. I can bring it up, but the record will reflect  
23 and you can take a look at it, if you wish, you made  
24 no attempt to correlate those media reports with the  
25 studies at issue in this case?

1 A. How would you do that?

2 Q. Well, you might say we have a couple of studies  
3 from Australia, and let's see whether or not there was  
4 any publicity in Australia.

5 A. When we're talking about Schildkraut, they  
6 didn't just say there was news reports. They  
7 literally had their own data to see whether that  
8 occurred. I can't do that even if you want me to.

9 Q. The next question is, let me talk about the  
10 issue of asbestos.

11 Would you agree with me, Doctor, there is no  
12 safe dose of asbestos in your experience?

13 A. I'd agree that there is no dose that's been  
14 demonstrated to be safe, but I know there has to be  
15 one.

16 Q. And putting the issue of causation aside, would  
17 you agree with me that if you are doing a Bradford  
18 Hill analysis and you are looking for biologic  
19 plausibility, you would agree with me on a couple of  
20 basic principles -- let me rephrase the question.

21 No. 1, asbestos is a known carcinogen?

22 A. That is correct.

23 Q. No. 2, there are studies linking ovarian cancer  
24 and asbestos?

25 A. There are with some challenges to them.

1 Q. No. 3, that IARC has taken the position that  
2 asbestos is an ovarian carcinogen?

3 A. Correct.

4 Q. No. 4, you are looking at talcum powder products  
5 in this case, and I think your phrase is "whatever  
6 constituents are contained in the product"?

7 A. Correct.

8 Q. Now, when you are looking at the association  
9 aspect of it, the statistical side of it, consistency  
10 strength, et cetera, it's baked into the epidemiology.  
11 Correct?

12 A. If we're talking about the epidemiology that  
13 relates perineal application of talcum powder and  
14 ovarian cancer. Is that correct? I'm trying to  
15 clarify because I want to make sure what question I'm  
16 answering.

17 Q. Yes, correct.

18 Let's take those statistical measures of  
19 epidemiology and put them aside for a minute and talk  
20 about biologic plausibility, which is the biology  
21 aspect of it.

22 Considering whether or not the association  
23 seen or suggested makes sense, you agree that's the  
24 definition of biologic plausibility. Correct?

25 A. It's reasonable to call it that.

1 Q. So if biologic plausibility, if the definition  
2 is: Does the association make sense from a biologic  
3 standpoint, if that is the definition, would the  
4 presence of a carcinogen or a probable carcinogen in  
5 the product, generally speaking, provide you with  
6 additional information, that would allow you to say  
7 this association we see, it makes sense it could be  
8 causal?

9 A. Not in this case, no.

10 Q. I'm asking generally speaking.

11 A. How does that work? I understand it's a  
12 hypothetical.

13 Q. In evaluating biologic plausibility, if I have a  
14 glass of soda and I drink it, and I get sick, and we  
15 find out in the soda there is chili powder, and  
16 somebody says, does it make sense that that soda made  
17 Chris sick, would the presence of chili powder help  
18 explain what happened to me?

19 A. Maybe. I don't know.

20 Q. You don't think it would?

21 A. I don't know. Does chili powder make you sick?

22 Q. All right. If I have a bottle of talcum powder  
23 and in this bottle are known carcinogens, and we have  
24 a pattern of epidemiology studies which demonstrate an  
25 increased risk, if I have a carcinogen in here, does

1 it help make sense in looking at the totality of the  
2 data that that may be an explanation?

3 A. Only in an abstract way. I think you would have  
4 to understand something about what kind of dose you  
5 are talking to see if it makes any sense at all.

6 Q. Dose goes to causation. Correct?

7 A. It can.

8 Q. I'm talking about biologic plausibility, which  
9 is a totally different concept; isn't it?

10 A. Not necessarily.

11 Q. But it can be?

12 A. Well, it is to me because if you said that there  
13 was a single fiber of asbestos in the bottle, and you  
14 were going to say, is that biologically plausible it  
15 causes cancer?, I would say, No. I don't know of any  
16 study that shows a single fiber can. So it's not  
17 enough to just know there's a single fiber. You would  
18 have to know something more about the dose.

19 Q. How many women do you know, Doctor, who use a  
20 bottle of baby powder once in their lifetime? These  
21 studies talk about lifetime use, daily use, weekly  
22 use. Correct?

23 A. Some do, yes.

24 Q. Some of these are over decades. Correct?

25 A. That's correct.

1 Q. If there is a fiber or two or five or ten in  
2 every bottle and use it for their lifetime, does that  
3 help you decide on biologic plausibility?

4 A. No. Dose is a very different concept than that  
5 just how many fibers are there. Dose literally means  
6 the amount of the substance that reaches the target  
7 organ.

8 Q. How many fibers does it take to cause  
9 mesothelioma?

10 A. No idea.

11 Q. Can one fiber cause changes that are consistent  
12 with mesothelioma?

13 A. Really doubtful.

14 Q. Can ten?

15 A. No idea.

16 Q. Would you agree with me that the presence of  
17 asbestos, for example, is relevant to the question of  
18 whether or not it is a biologically plausible  
19 mechanism for causing ovarian cancer?

20 A. Not without knowing something about the dose  
21 that you are talking about.

22 Q. Do you know that PCPC on behalf of the talc  
23 industry presented a report to the FDA in 2009 on the  
24 issue of ovarian cancer in talc?

25 MS. BROWN: Objection, your Honor, to the

1 relevance of this.

2 MR. LOCKE: I also object for lack of  
3 foundation.

4 THE COURT: What's the basis, Mr. Tisi?

5 MR. TISI: Let me go to a published article.

6 THE COURT: Okay.

7 BY MR. TISI:

8 Q. Are you familiar with an article by Huncharek  
9 and Muscat?

10 MR. TISI: I apologize. I grabbed the part  
11 that did not have a highlight.

12 A. I don't believe I have seen this one before.

13 MS. BROWN: Is it in the binder, counsel?

14 MR. TISI: It is.

15 Q. If you go to page 505.

16 THE COURT: What exhibit?

17 MR. TISI: Exhibit 155, your Honor.

18 THE COURT: What page?

19 MR. TISI: Page 505.

20 Q. This is a review, and I will represent to you  
21 that this was an article that was authored by people  
22 who were both consultants and expert witnesses for  
23 J&J.

24 If you look at page 505, three-quarters of the  
25 way down, there is a statement that begins with, "A

1 number of investigators."

2 Do you see that?

3 A. I do.

4 Q. Go to page 505. It says:

5 "A number of investigators initially  
6 implicated talc products as possible carcinogens, as  
7 before the early 1970s some talc products contained  
8 small amounts of asbestos fibers. Clearly, such  
9 products could possibly represent a carcinogenic risk  
10 secondary to asbestos contamination. It should be  
11 pointed out that this in no way implicates talc as a  
12 toxin if the problematic constituent of such products  
13 was asbestos fibers, not talc."

14 Do you see that?

15 A. I do.

16 Q. Putting aside the issue whether or not talc or  
17 other constituents may be carcinogenic. If it  
18 contains asbestos, that is at least a biologic  
19 explanation for the epidemiology. Is that not  
20 correct?

21 A. Two things: One, you still need the dose. But  
22 they are also citing an article Rohl, which has been  
23 found to be unreliable. That particular study has  
24 been found to be unreliable because they couldn't  
25 distinguish asbestiform from non-asbestiform fibers.



1 The premise here is based on something --

2 MR. TISI: I move to strike.

3 Q. I'm asking you the question about whether or not  
4 the presence of asbestos in talc can provide a  
5 biologic plausible explanation that would be  
6 consistent with the causal inference.

7 A. I think I've already answered that. This isn't  
8 any different just because we read this. My answer  
9 stands from what I said before.

10 Q. Your answer would be yes, that it could.

11 MS. BROWN: Objection, your Honor. That  
12 misstates what he testified to before.

13 THE COURT: I'll let him give his answer now.

14 BY MR. TISI:

15 Q. The question is: If there is presence of  
16 asbestos in the talc could that provide a biologically  
17 plausible explanation that is consistent with the  
18 causal inference?

19 A. I would say no unless you can tell me something  
20 about what that dose would be.

21 Q. I want to ask you a couple of questions about  
22 the -- do you know whether or not the other day in  
23 court, where you were told that another trial that a  
24 corporate representative of J&J --

25 MS. BROWN: Objection, your Honor. It sounds

1 like counsel is about to give information about  
2 testimony of a J&J corporate representative. I would  
3 object as inappropriate for this context, lacking  
4 foundation, and irrelevant to the inquiry before the  
5 Court and to Dr. Diette's testimony.

6 MR. TISI: It's not irrelevant, your Honor.

7 THE COURT: Let me hear what you are trying to  
8 do. I ruled before about the J&J documents testing  
9 and did not admit them. What are you trying to do now  
10 that changes that?

11 MR. TISI: I'm trying to demonstrate that J&J  
12 has taken the position that there is no safe dose of  
13 asbestos, none, not a fiber, not 20 fibers, not 100  
14 fibers, and J&J's corporate representative --

15 THE COURT: Even if you say that this expert  
16 may not agree with it anyway. We're dealing with his  
17 opinions. He's already says he disagrees. Leave it  
18 to that and ask him his opinions.

19 BY MR. TISI:

20 Q. Doctor, do you know whether or not a reasonable  
21 scientist looking at that question could reach a  
22 contrary conclusion?

23 A. So I'm clear, can you say what that question is?

24 Q. A reasonable expert looking at talcum powder  
25 products, if it contains asbestos or a known or

1 potential carcinogen would be relevant to the issue of  
2 biologic plausibility?

3 THE COURT: I think you are asking the  
4 question regardless of dose.

5 Q. Regardless of dose. One fiber. Is one fiber --

6 A. I think a reasonable scientist would not be on  
7 firm ground if their opinion was a single fiber would  
8 cause cancer.

9 Q. Ten fibers?

10 A. I don't know what the threshold would be.

11 Q. Where would you be comfortable?

12 A. I would be comfortable if you could tell me what  
13 the dose was that the person received from the  
14 exposure that you are talking about.

15 Q. You don't know how many fibers it would take to  
16 make it biologically plausible?

17 A. No. You still would have to translate it into a  
18 dose.

19 MR. TISI: Your Honor, I have no further  
20 questions. Thank you very much.

21 MS. BROWN: With the Court's indulgence, I  
22 have ten minutes of redirect.

23 THE COURT: That's fine.

24 REDIRECT EXAMINATION

25 BY MS. BROWN:

1 Q. Just a few questions for you to finish out the  
2 day.

3 I want to start by picking up where counsel  
4 left off regarding a hypothetical asbestos  
5 contamination of talcum powder.

6 Are you with me?

7 A. I am.

8 Q. When we heard from Dr. McTiernan yesterday she  
9 testified whether talcum powder is contaminated with  
10 any alleged constituent or not, the relevant body of  
11 epidemiology to look to try to determine if there is a  
12 causal association between talc and ovarian cancer, is  
13 the talc epidemiology. Do you agree with that?

14 A. I do.

15 Q. Tell us why.

16 A. First of all, because it's what we have. I  
17 don't know if there is even a single study that  
18 characterized what the powder -- what it contained.  
19 In some cases the studies talked about powder that  
20 either was or wasn't talc. But even when it was talc,  
21 for the most part it wasn't identified as what the  
22 constituents were.

23 So I think we are left with whatever was  
24 assessed as talcum powder application is what it is.  
25 Everything about it, whether it's pure or not pure,

1     whatever that means, is really part of the  
2     epidemiology.

3     Q.     Counsel asked you some questions about a slide  
4     you and I put up about IARC. Do you remember that?

5     A.     I do.

6     Q.     And the slide that you and I put up actually  
7     regarding IARC was not the one counsel showed you, was  
8     it?

9     A.     That's correct.

10    Q.     What you and I put up in fact was IARC's  
11    definition of the 2-B classification. Is that right?

12    A.     Yes, this is part of the conclusion.

13    Q.     And in classifying talc in the 2-B category,  
14    what are the issues that IARC raised as it relates to  
15    the evidence or the quality of the evidence of  
16    carcinogenicity?

17    A.     They said that chance bias or confounding could  
18    not be ruled out with reasonable confidence.

19    Q.     And what was the year of this IARC monograph?

20    A.     It was published in 2010.

21    Q.     Does that remain the IARC classification today?

22    A.     Yes.

23    Q.     And one of the articles that you discussed with  
24    the Court this morning regarding recall bias was the  
25    Schildkraut article. Is that correct?

1 A. It is.

2 Q. Do you recall the year the Schildkraut article  
3 was published?

4 A. It looks like 2016 is the copyright.

5 Q. Did IARC have the benefit of the Schildkraut  
6 results in 2010?

7 A. No.

8 Q. You were asked some questions, Dr. Diette, about  
9 a textbook by a Dr. Rothman. Do you remember that?

10 A. I do.

11 Q. And you were asked some questions about whether  
12 it would be appropriate to look at cohort studies to  
13 the exclusion of case-control studies or above and  
14 beyond case-control studies. Do you recall that?

15 A. I do.

16 Q. In performing your Bradford Hill analysis in  
17 this case, did you do that?

18 A. No. I looked at all the studies of both  
19 designs.

20 Q. Did Dr. Rothman, though, actually look at the  
21 talc epidemiology?

22 A. He did.

23 Q. And did he publish a paper about his  
24 interpretation of the talc epidemiology?

25 MR. TISI: Objection, your Honor, to the

1 phrase "publication." This is a report I was going to  
2 use if you allow me to redirect on it, I'm happy to  
3 allow her to use it, but it has not been published.

4 THE COURT: It's not published?

5 MR. TISI: It's not published. It's a report  
6 submitted to the National Toxicology Program.

7 THE COURT: You said in your question --

8 MS. BROWN: I'll rephrase.

9 BY MS. BROWN:

10 Q. Are you aware of a report by Dr. Rothman  
11 regarding the talc epidemiology in 2000?

12 A. Yes.

13 Q. Did Dr. Rothman comment on whether the relative  
14 risk seen at that time of 1.31 was strong or weak?

15 A. He used the characterization "weak."

16 Q. And is that consistent with your understanding  
17 of how a properly-applied Bradford Hill methodology  
18 would view a 1.2 or a 1.3 relative risk?

19 A. It is.

20 Q. And does Dr. Rothman also indicate some  
21 potential concerns or challenges to interpreting a  
22 relative risk of 1.3?

23 A. Yes. He said that bias and causation are  
24 competing explanations for the weak/positive  
25 association.

1 Q. And is that consistent with the, Doctor, with  
2 IARC's classification of the talc epidemiology?

3 A. Yes.

4 Q. And did Dr. Rothman also comment on whether or  
5 not the talc epidemiology indicated a dose-response?

6 A. If you look at the very top there, one of the  
7 things he notes is that a nearly constant feature of  
8 causal relations in epidemiology and in pathogenesis  
9 of cancer, in particular, is a monotonically  
10 increasing relation between measures of exposure and  
11 disease risk.

12 And then what he did is estimated what the  
13 curves looked like, two different curves, and found  
14 they were inversed, meaning the more you used, they  
15 would appear protective from ovarian cancer.

16 Q. Is Dr. Rothman's finding on the lack of a  
17 dose-response consistent with your review of the talc  
18 epidemiology?

19 A. That summarizes at the time some of the findings  
20 which at that point looked more inverse rather than  
21 flat or positive.

22 Q. Since the publication of Doctor --

23 MR. TISI: I object to the term "publication."

24 MS. BROWN: I'll rephrase it.

25 BY MS. BROWN:



1 Q. Since 2002 have you reviewed the talc  
2 epidemiology as it relates to whether or not a  
3 dose-response has been seen?

4 A. Yes.

5 Q. And have you found a consistent dose-response?

6 A. Not a consistent one.

7 Q. You were shown a draft screening assessment from  
8 Health Canada. Do you remember that?

9 A. I do.

10 Q. And does Health Canada in fact make a statement  
11 regarding biological gradient or dose-response?

12 A. Yes.

13 Q. And what is the conclusion as recently as  
14 December 2018 of Health Canada regarding whether or  
15 not the talc epidemiology evidence is a dose-response?

16 A. There are a couple just to -- the first sentence  
17 states that there is a lack of an available exposure  
18 effect relationship in the human epidemiological data.

19 And they also talk about Taher and colleagues  
20 isolated seven studies that provided some evidence of  
21 increased risk of ovarian cancer with increasing  
22 perineal applications of talc. However, none  
23 demonstrated both a clear dose-response, and I think  
24 the next page says "and statistical significance."

25 Q. Is that consistent, Doctor, with your

1 application of the Bradford Hill methodology?

2 A. It is.

3 Q. You were asked some questions, Doctor, about  
4 whether this draft screening assessment was  
5 peer-reviewed. Do you remember that?

6 A. I do.

7 Q. And does the draft screening assessment in fact  
8 contain a sentence regarding what -- a statement as to  
9 that peer-reviewed process?

10 A. Let's see. I know we saw it earlier.

11 Q. The sentence beginning on the bottom of one of  
12 the risk assessment, and going to two:

13 "The human health portion of this assessment  
14 has undergone external peer review and/or  
15 consultation?"

16 Do you see that?

17 A. I do.

18 Q. Does the draft "Screening Assessment" report any  
19 additional information about what this external peer  
20 review and/or consultation may have looked like?

21 A. I didn't see anything else.

22 Q. The draft "Screening Assessment" goes on to  
23 state:

24 "This draft Screening Assessment focuses on  
25 information critical to determining whether substances

1 meet the criteria as set out in Section 64 of CEPA by  
2 examining scientific information and incorporating a  
3 weight of the evidence approach and precaution."

4 Do you see that, Doctor?

5 A. I do.

6 Q. And is there additional information available on  
7 Health Canada's website regarding what Health Canada  
8 views as required for this precautionary approach?

9 A. Yes, it's this document that you have that I  
10 have seen.

11 Q. And this is Health Canada decision-making  
12 framework for identifying, assessing and managing  
13 health risks.

14 Does it not give information about the use of  
15 a precautionary approach?

16 A. Yes.

17 Q. A key feature of managing health risks is that  
18 decisions are often made in the presence of  
19 considerable scientific uncertainty. Is that correct?

20 A. That's right.

21 Q. (Reading.)

22 "A precautionary approach to decision-making  
23 emphasizes the need to take timely and appropriate  
24 preventative action even in the absence of a full  
25 scientific demonstration of cause and effect."

1           Is that how the Health Canada organization  
2 described its precautionary approach?

3           MR. TISI: Your Honor, let me object. Counsel  
4 went beyond. I focused on the scientific portion of  
5 the Health Canada. She's focusing on the regulatory  
6 application of it, which are two different parts, and  
7 it's very misleading. Health Canada had two goals  
8 here, and I specifically stayed away from the one.  
9 One is whether or not it needed to take regulatory  
10 action under Canadian law to warn women and take  
11 remedial steps. That's where the precautionary issue  
12 comes into being.

13           The scientific analysis, which was a Bradford  
14 Hill analysis that you saw, is a separate -- was a  
15 separate analysis. I think it's misleading to  
16 conflate the two. I know this is a hearing, and we  
17 can do whatever we want in the hearing. There is no  
18 jury present, but it's misleading because that is not  
19 what the document says.

20           MS. BROWN: Your Honor, we are working off the  
21 document --

22           THE COURT: It sounds more like Mr. Tisi  
23 thinks you are going into an area that's not  
24 appropriate for redirect. That's what I was hearing.

25           MR. TISI: Both. A, it's inappropriate, and,

1 B, it's misleading.

2 THE COURT: I don't know if it's misleading.  
3 She is reading right from the document.

4 MR. TISI: I focused on the scientific aspect  
5 of it, which is the Bradford Hill aspect. She's going  
6 to the regulatory issues at Health Canada. If you  
7 look at the synopsis, the paragraph I read, which was  
8 the scientific aspect of it -- and that's why I took a  
9 little bit of time to go through and say which is the  
10 portion that was peer-reviewed, and it was the health  
11 effect section.

12 The other section of the document deals with  
13 the Canadian Act, whatever. And if you look at the  
14 very last paragraph that follows the scientific  
15 conclusion, they talk about, Now that we have this  
16 result, what do we do with it? I don't have the  
17 document in front of me.

18 THE COURT: Isn't that the point of it? The  
19 reason they went about this is to decide to take  
20 action. It's the same thing of anything we talk  
21 about, about the governmental documents, IARC. The  
22 reason these reviews are being undertaken by a  
23 governmental agency, here Health Canada, is to decide  
24 is there some action to be taken; if it's IARC, how do  
25 we classify it, what do we do.

1 I don't think it's inappropriate. Let's hear  
2 it and move on. I will give you a few minutes of  
3 redirect just as I gave yesterday to Mr. Williams.  
4 It's not late in the day. We'll go a little longer.

5 MS. BROWN: I can conclude quickly.

6 BY MS. BROWN:

7 Q. The two points here, Dr. Diette, is counsel  
8 represented that this document has been peer-reviewed;  
9 and based just on the text of what we have regarding  
10 the review process, is it clear from the document  
11 itself whether it had been externally peer-reviewed or  
12 there was some kind of consultation the details of  
13 which we don't know?

14 A. It's hard to tell whether it's either/or both.

15 Q. And in terms of the focus of the draft-screening  
16 assessment regarding the scientific information and  
17 the approach to weighing the evidence, does Health  
18 Canada speak to a precautionary approach?

19 A. They do.

20 Q. Does that precautionary approach that we just  
21 looked at, where a preventive action can be taken in  
22 the absence of full scientific demonstration of cause  
23 and effect, is that consistent -- or I think counsel  
24 used the term "very similar" or "almost the same" as a  
25 Bradford Hill causal analysis?

1 A. No, it clearly doesn't require a causal  
2 conclusion, that it's something that can come up short  
3 of that.

4 Q. Counsel asked you some questions about whether,  
5 well, Health Canada had done the same thing you had,  
6 and the two of you just reached separate conclusions.

7 In your review of the Health Canada document  
8 and the precautionary approach that they took, was  
9 Health Canada, the folks at Health Canada, employing  
10 the same Bradford Hill criteria as you employed?

11 MR. TISI: Objection. Leading I guess is  
12 okay.

13 MS. BROWN: I'll rephrase.

14 THE COURT: Leading has been the name of the  
15 game in most of the direct that I've heard this week.

16 Go ahead.

17 BY MS. BROWN:

18 Q. How would you compare, Dr. Diette, the Bradford  
19 Hill methodology that you employed here with the  
20 precautionary approach that Health Canada took in its  
21 assessment?

22 A. I'd say a couple of things. One was I didn't  
23 see they actually assessed each one of the criteria.  
24 That was one difference.

25 But the purpose of Bradford Hill is to

1 determine causation, and so it's a different exercise  
2 that precautionary principle in general requires  
3 somebody to, in essence, raise concern, but not to  
4 have definitive proof or even a substantial evidence  
5 of causation to take some action.

6 Q. Dr. Diette, counsel spent a fair amount of time  
7 asking you questions about consistency. Do you recall  
8 that?

9 A. I do.

10 Q. Do you recall questions suggesting you had made  
11 a determination the epidemiology was inconsistent  
12 based on a review of whether there was statistical  
13 significance in the case-control studies?

14 MR. TISI: Your Honor, I didn't even ask her  
15 about this slide. I think you gave counsel ten  
16 minutes.

17 THE COURT: She said she only needed ten.  
18 Let's be fair. The rule has been that on the redirect  
19 we talked about it, what time could be spent. I  
20 clearly indicated you could have a half hour, an hour.  
21 She just indicated she thought she only needed  
22 ten minutes. That is why we went through instead of  
23 taking a break.

24 MS. BROWN: This is the last topic.

25 THE COURT: It wasn't because she was only



1 allotted that.

2 BY MS. BROWN:

3 Q. Do you recall those questions about consistency  
4 and how you had made your determination of whether or  
5 not there was consistency in the talc epidemiology?

6 A. Yes.

7 Q. Dr. Diette, remind us the areas that you  
8 considered in reaching your determination about  
9 consistency.

10

11 A. Several, but looking at the total evidence that  
12 was available and what we had put up here were some  
13 examples of there being differences by study design,  
14 so that the retrospective did and the prospective did  
15 not show an association, that condoms and diaphragms  
16 contrary to what one might think did not have a  
17 consistent association with ovarian cancer, that the  
18 dose-response was really all over the map as we  
19 discussed before, tubal ligation should interrupt,  
20 wasn't consistently protective in the studies, and  
21 NSAIDS, which are antiinflammatories are not  
22 consistently associated with reduction and risk as  
23 they might be, and in fact may be associated with  
24 higher risk.

25 Q. Did you make your determination that there was

1 no consistency based solely on a review of whether or  
2 not a study reached statistical significance or did  
3 not?

4 A. No. I evaluated whether each one did or not.  
5 But I didn't reach my evaluation of consistency solely  
6 based on that.

7 Q. Did you reach your conclusions about the talc  
8 epidemiology by elevating cohort studies to the  
9 exclusion of case-control study?

10 A. No.

11 Q. Did you consider the totality of the  
12 epidemiological evidence as it relates to the  
13 hypothesis that talc can cause ovarian cancer?

14 A. Absolutely.

15 Q. Do you believe that someone properly applying  
16 the Bradford Hill criteria could possibly reach a  
17 different result than you did in this case?

18 A. No.

19 MS. BROWN: I have no further questions.

20 THE COURT: I'll give you a few minutes,  
21 Mr. Tisi.

22

23 RECROSS-EXAMINATION

24 BY MR. TISI:

25 Q. Counsel asked you some questions about -- and

1 I'm glad she did ask you some questions about --  
2 Dr. Rothman's report in 2000. This 2000 report is  
3 19 years ago in terms of the studies that have gone on  
4 between then and now. Correct?

5 A. Correct.

6 Q. But the general principles that he describes  
7 here are all the same. Correct? The methods?

8 A. I don't remember every word of that, but,  
9 certainly, at least many of the principles are the  
10 same.

11 Q. If you go to the second page of the document,  
12 this is Exhibit 146, under "Exposure  
13 Misclassifications," do you see that?

14 A. Not yet.

15 Q. It's on page 3.

16 A. Okay.

17 Q. J&J and PCPC and the talc industry hired  
18 Dr. Rothman to present this to the National Toxicology  
19 Program? This was J&J's expert at the time.

20 A. I heard that. I'm not sure whether it's right  
21 or not.

22 Q. They didn't contact you at any time to do this  
23 for them, right?

24 A. That is correct.

25 Q. But they did contact Dr. Rothman, and Dr.

1 Rothman here says:

2 "It is commonly believed that the validity of  
3 case-control study is worse than cohort studies, but  
4 that view is a mistaken."

5 Do you see that?

6 A. I do.

7 Q. (Reading.)

8 "The validity of the study depends on the  
9 specifics of the study design, the nature of the data,  
10 and the nature of the hypothesis the study addresses."

11 Do you see that?

12 A. I'm with you.

13 Q. The truth of the matter is, because of the  
14 nature of cancer, many of the studies of cancer are  
15 case-control studies. True?

16 A. For rare cancers especially.

17 Q. Ovarian cancer is a rare cancer; isn't it?

18 A. It is.

19 Q. So it's not surprising that the studies that are  
20 the ones that are most used by people who study the  
21 epidemiology of cancers are case-control studies.

22 True?

23 A. It's not surprising.

24 Q. He gives an example, and this is helpful:

25 "A cohort study that examines the long-term

1 risk of cancer among coffee drinkers after a one-time  
2 dietary assessment of coffee consumption would suffer  
3 from weak exposure assessment. Although exposure  
4 information might be accurate at the time it was  
5 collected the exposure status of the cohort members  
6 will change over time with time and the initial  
7 measure might only poorly correlate with more  
8 meaningful measures of coffee consumption."

9 What he is saying here is, Doctor, if you only  
10 take the measurement once, that people's behavior  
11 changes. Right?

12 A. It can change.

13 Q. Often does change. Correct?

14 A. I don't know how often it does, but it can  
15 change, is the point.

16 Q. (Reading.)

17 "The effect of having a poor measure of  
18 exposure will be considerable nondifferential  
19 misclassification."

20 He uses the word "considerable." Correct?

21 A. That's correct.

22 Q. Now, adding to that let's say instead of  
23 studying coffee consumption, you want to study  
24 caffeine consumption, and you ask people about coffee.

25 Now, if you ask them about coffee, they may

1 answer if you are not specific enough, you would  
2 include decaffeinated coffee. Right?

3 A. I'm sorry?

4 Q. If the questionnaire says, You drink coffee,  
5 people --

6 A. I understand. I misheard. This has been on my  
7 mind since the Health Canada thing, which is they say  
8 that there's 8,500 consumer products that have talc in  
9 it. That's like asking about perineal talcum powder  
10 and not asking about the 8,499 other ones.

11 Q. But you know the cohort studies, Houghton and  
12 Gates, asked only once. Right?

13 A. Correct.

14 Q. And not only that, but they only asked about  
15 powder exposure. It could be cornstarch. It could be  
16 other kinds of powders. Right?

17 A. I would have to look back to see which question  
18 was used on which, but I know certain studies used  
19 that broader.

20 Q. And so both of those things combined have the  
21 potential of raising nondifferential or, to use Dr.  
22 Rothman's term, considerable nondifferential  
23 misclassification. Correct?

24 A. Correct.

25 Q. And that is the kind of bias -- you spent a lot

1 of time talking about recall bias, but that's the kind  
2 of bias that's towards the null?

3 A. That is correct.

4 Q. And that is a point that Dr. Rothman is making.

5 Another thing he says here, he talked about  
6 another issue you raised, which is the issue of  
7 confounding. This is 19 years ago:

8 "Although there are some strong risk factors  
9 for ovarian cancer, for any of them to be confounding  
10 to the extent they could account for the positive  
11 relations that have been reported, they would have to  
12 be strongly correlated with talc use. Family history,  
13 ethnicity, obesity, and some reproductive factors are  
14 poorly associated with the risk of ovarian cancer."

15 See that?

16 A. I do.

17 Q. (Reading.)

18 "But the magnitude of these associations does  
19 not appear to be high enough to induce enough  
20 confounding, even jointly, to completely explain the  
21 positive association?"

22 Do you see that?

23 A. I do.

24 Q. So what he is saying is, in order for the  
25 confounder to really explain the results of the study,

1 the confounder has to be closely correlated with, in  
2 this case talc use, closely correlated causing the  
3 disease itself, and it would have to be of an order of  
4 magnitude that would have to be high enough to explain  
5 the risk. Correct?

6 A. To be fair, they list four that they say the  
7 magnitude does not appear high enough to induce enough  
8 confounding. But we know most of the explanation for  
9 ovarian cancer isn't known. So the majority of the  
10 risk remains to be discovered, and all of that could  
11 be confounding.

12 Q. But what he is saying and whether you see IARC,  
13 whether you see Dr. Rothman, whether the study we  
14 talked about before, confounding has consistently been  
15 said unlikely done, unlikely the result to be a cause  
16 of the increased risk for the talc study. You have  
17 seen that in the literature. Correct?

18 A. I don't think what you said is right. We've  
19 looked at a variety of different statements on it.  
20 Some consider it possible. There is different  
21 language that different investigators have used.

22 Q. Counsel asked you about precautionary principles  
23 in Health Canada, and I'm going to ask -- let me ask  
24 you briefly.

25 Health Canada specifically excluded discussion



1 of asbestos in talc. Right?

2 A. They were focused on talc for this project.

3 Q. And did they say that if talc was in the  
4 asbestos, that they would categorize it in a  
5 completely different way?

6 A. I think you meant the other way around. I think  
7 you said if talc was in the asbestos.

8 Q. If asbestos was in talc, it would be a  
9 completely different issue and it would be governed by  
10 a different set of regulations?

11 A. I don't recall that, but I don't doubt that it  
12 would be a different mechanism.

13 Q. And so at least to Health Canada, the presence  
14 or absence of asbestos in talc would have made a  
15 difference. Correct? You saw that in the document.

16 A. In how they regulate it?

17 Q. Yes.

18 A. Yes.

19 Q. One other thing, in terms of what Health Canada  
20 -- in terms of precautionary principles, do you know  
21 what Health Canada is proposing to tell consumers  
22 about the risk of talc?

23 A. Beyond what is in these documents we looked at  
24 today?

25 Q. Yes. Did you look on the website?

1 THE COURT: He already said he doesn't know.  
2 Let's move on.

3 MR. TISI: So the record is clear --

4 THE COURT: No. We're dealing with the  
5 document. It's not part of what he's got. He only  
6 testified about the document.

7 Let's move on. You are not going to get it  
8 through him.

9 MR. TISI: I have no further questions.  
10 Thank you for your indulgence.

11 THE COURT: Thank you.

12 You are excused, Dr. Diette.

13 (Witness excused.)

14 (Court adjourned at 3:30 p.m.)

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I N D E X

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Gregory B. Diette

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By Mr. Tisi

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C E R T I F I C A T E

PURSUANT TO TITLE 28, U.S.C., SECTION 753, THE  
FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE  
TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE  
ABOVE-ENTITLED MATTER.

S/Vincent Russoniello  
Vincent Russoniello, CCR  
Certificate No. 675

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